

[ORAL ARGUMENT NOT SCHEDULED]**No. 20-5331**

**IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

WHITMAN-WALKER CLINIC, INC., et al.,**Plaintiff-Appellees,****v.****UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
et al.,****Defendants-Appellants.**

**On Appeal from the United States District Court
for the District of Columbia**

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

WHITMAN-WALKER CLINIC, Inc. d/b/a
WHITMAN-WALKER HEALTH
1377 R Street NW
Washington, DC 20009;

Case No.

THE TRANSLATIN@ COALITION
3055 Wilshire Boulevard, Suite 350
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COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

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Plaintiffs,)

v.)

U.S. DEPARTMENT OF HEALTH AND)
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200 Independence Avenue SW)
Washington, D.C. 20201;)

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Secretary of U.S. Department of Health and)
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Defendants.)

INTRODUCTION

1. A person's access to health care should not be contingent on their sex, gender identity, transgender status, sexual orientation, race, national origin, age, disability, or religion. When people go to a doctor's office, hospital, or an emergency room seeking treatment, they expect and are entitled to receive care appropriate to meet their health needs without regard to who they are or the type of health care they seek.

2. Yet, in the midst of a global pandemic, the Trump Administration's Department of Health and Human Services ("HHS") has sought to diminish protections from discrimination in health care because of a person's sex, gender identity, transgender status, sexual orientation, race, national origin, age, or disability.

3. HHS has taken these actions notwithstanding and despite the decision of the Supreme Court of the United States on June 15, 2020 holding that discrimination on the basis of a person's transgender status or sexual orientation is discrimination on the basis of sex. *See Bostock v. Clayton Cty., Ga.*, 590 U.S. ___, 2020 WL 3146686 (June 15, 2020).

4. As of the filing of this Complaint, and in less than six months, approximately 2.25 million people in the United States have tested positive for COVID-19, resulting in approximately 120,000 deaths to date.¹ The United States is facing a public health crisis. During these difficult times, Americans need the security and peace of mind that they will be able to access the health care they need and require. The government should be doing everything within its capacity to protect and preserve the safe and effective delivery of health care to all patients regardless of their sex, gender identity, transgender status, sexual orientation, race,

¹ Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19): Cases in the U.S.*, <https://perma.cc/38HG-JUBB> (last visited June 21, 2020).

national origin, age, or disability. Yet, HHS is doing exactly the opposite, adopting positions that fly in the face of its stated mission to “enhance and protect the health and well-being of all Americans by providing for effective health and human services.”²

5. Recognizing the paramount importance of providing people with prompt, effective, and nondiscriminatory access to health care, Congress has taken repeated and concerted efforts to improve access to health care and bar discrimination within the health care industry.

6. Section 1557 of the Patient Protection and Affordable Care Act (“ACA”), 42 U.S.C. § 18116, specifically and explicitly protects against discrimination in the provision of health care services. Section 1557 prohibits discrimination based on sex, race, color, national origin, age, and disability.

7. In 2016, HHS promulgated a final rule, developed over the course of six years and two notice-and-comment periods, to implement the nondiscrimination requirements of Section 1557. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (May 18, 2016) (formerly codified at 45 C.F.R. pt. 92) (the “2016 Final Rule”). Consistent with Section 1557’s nondiscrimination mandate, the 2016 Final Rule made clear that health care providers and insurers may not discriminate against lesbian, gay, bisexual, transgender, and queer (“LGBTQ”) people in making medical and coverage decisions. Doing so constitutes discrimination on the basis of sex, which the 2016 Final Rule specifically defined to include discrimination on the basis of gender identity and sex stereotyping, among other criteria.

² U.S. Dep’t of Health & Human Servs., *About HHS*, HHS.GOV, <https://perma.cc/CY5N-RBPH>.

8. The 2016 Final Rule also included specific guidance about how Section 1557's sex discrimination prohibition applies to transgender people, including access to and coverage of gender-affirming health services.

9. In addition, the 2016 Final Rule confirmed, based on the plain statutory language of Section 1557, that all enforcement mechanisms available under the statutes listed in Section 1557 are available to any person regardless of the person's protected characteristic, establishing a unitary legal standard for all violations of the statute. It also confirmed that Section 1557 prohibits not only intentional discrimination, but conduct and practices that have the effect of subjecting individuals to discrimination on the basis of their sex.

10. Since the 2016 Final Rule went into effect, it has led to a dramatic decrease in discriminatory policies and practices.³

11. Now, however, with next-to-no legal, medical, or reasoned policy foundation, and contrary to the opinions of professional medical and public health organizations,⁴ HHS has issued a revised regulation under Section 1557 (the "Revised Rule") that rolls back the 2016 Final Rule and limits the protections for LGBTQ people, among others. *See* Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg.

³ *See, e.g.,* Sharita Gruberg and Frank J. Bewkes, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial*, Center for American Progress (Mar. 7, 2018), <https://perma.cc/CTP2-UMEJ>.

⁴ *See, e.g.,* Letter from James L. Madara, MD, Exec. Vice President/CEO, American Medical Association, to The Hon. Alex M. Azar II, Sec'y, U.S. Dep't Health & Hum. Servs. (Aug. 13, 2019), <https://perma.cc/9N7N-JJ3G>; Letter from Saul Levin, MD, MPA, FRCP-E, CEO & Med. Dir., American Psychiatric Association, to Sec'y Alex Azar II, U.S. Dep't Health & Hum. Servs. (Aug. 9, 2019), <https://perma.cc/YUG9-E6SW>; Letter from Katherine B. McGuire, Chief Advocacy Officer, American Psychological Association, to U.S. Dep't Health & Hum. Servs. (Aug. 13, 2019), <https://perma.cc/LE65-6Q63>.

37,160 (June 19, 2020) (to be codified at 42 C.F.R. pts. 438, 440, & 460 and 45 C.F.R. pts. 86, 92, 147, 155, & 156).

12. Although the Revised Rule cannot change the law, it is part of the Trump Administration's concerted and aggressive effort to undermine protections for LGBTQ people, including Section 1557's nondiscrimination protections and the regulatory structure and administrative processes the 2016 Final Rule established. Multiple provisions in the Revised Rule threaten to confuse and mislead patients, health care providers, and insurers and will result in increased discrimination and substantial harm to precisely those vulnerable communities that Section 1557 is intended to protect, like LGBTQ people and their families.

13. Relying on essentially one federal district court opinion, the Revised Rule arbitrarily and capriciously repeals entirely the 2016 Final Rule's definition of discrimination on the basis of sex, which specifically included discrimination based on gender identity and sex stereotyping, as well as related provisions prohibiting discrimination against transgender individuals. The elimination of this definition not only invites health care insurers and providers to discriminate against LGBTQ people seeking health care, but it also introduces substantial confusion among health care providers and insurers regarding their legal obligations and the right of the populations they serve to be free from sex discrimination, particularly in light of the Supreme Court's decision in *Bostock v. Clayton County, Georgia*, 590 U.S. ___, 2020 WL 3146686, which held that discrimination based on transgender status or sexual orientation "necessarily entails discrimination based on sex." *Id.* at *11.

14. The Revised Rule, which HHS publicly released three days prior to the Supreme Court's ruling in *Bostock*, recognizes that "a holding by the U.S. Supreme Court on the meaning of 'on the basis of sex' under Title VII will likely have ramifications for the definition of 'on the

basis of sex’ under Title IX,” because “Title VII case law has often informed Title IX case law with respect to the meaning of discrimination ‘on the basis of sex.’” 85 Fed. Reg. 37,168.

However, undeterred from their goal to foster discrimination against LGBTQ people, HHS published the Revised Rule, without any changes, four days after the Supreme Court’s decision in *Bostock*.

15. To be clear, *Bostock*’s holding that discrimination on the basis of sexual orientation or transgender status constitutes discrimination on the basis of sex forecloses HHS’s attempts to deny the full protection of Section 1557 to LGBTQ individuals and patients in health care settings.

16. The Revised Rule also eliminates the unitary legal standard for enforcement of violations of Section 1557, replacing it with a fractured approach that will complicate and make it more difficult to bring discrimination claims under Section 1557, particularly claims of intersectional discrimination. The Revised Rule’s elimination of the explicit recognition of private rights of action and the availability of compensatory damages under Section 1557 also will confuse the public and mislead individuals into not asserting their legal rights.

17. In addition, the Revised Rule imports broad and sweeping exemptions for discrimination based on personal religious or moral beliefs from the identified statutes in Section 1557 *and* other statutes, including the Religious Freedom Restoration Act (42 U.S.C. § 2000bb *et seq.*), which Section 1557 does not reference. These exemptions invite individual health care providers, health care entities, and insurers across the country to opt out of treating patients, including many transgender patients, if they believe doing so would compromise their faith.

18. These exemptions will adversely affect health care providers that serve and treat the LGBTQ community and their LGBTQ patients because (1) their individual health care

employees may decline to serve patients based on religious objections, and (2) their ability to refer patients to other providers will be impaired, as the Revised Rule would invite discrimination against their LGBTQ patients.

19. HHS’s attempt to create new religious exemptions in Section 1557 is contrary to law and endangers patients’ health in the name of advancing the religious beliefs of those who are entrusted with caring for them—a result sharply at odds with HHS’s stated mission to “enhance and protect the health and well-being of all Americans” and to “provid[e] for effective health and human services.”⁵

20. The Revised Rule also arbitrarily and capriciously eliminates the requirement that covered entities post notices informing individuals about nondiscrimination requirements and their rights and also cuts back the safeguards that the 2016 Final Rule implemented for patients with Limited English Proficiency (“LEP”), weakening protections for LEP patients and depriving families and individuals of adequate care.

21. In addition, the Revised Rule limits the scope of Section 1557, cutting back on the entities subject to Section 1557. Despite the plain language of Section 1557, the Revised Rule excludes health programs and activities that HHS funds but are not established or administered under Title I of the ACA and health insurance plans outside of Title I of the ACA that do not receive Federal financial assistance. Not only is this action inconsistent with Section 1557, it will cause drastic reductions in protections for LGBTQ people.

22. The Revised Rule also amends a series of unrelated regulations issued under statutes other than Section 1557 by deleting references to sexual orientation and gender identity discrimination. HHS does not have the authority to make these changes within the rulemaking

⁵ U.S. Dep’t of Health & Human Servs., *About HHS*, HHS.GOV, <https://perma.cc/CY5N-RBPH>.

challenged, and these changes are not supported by any analysis or evidence. The Revised Rule is intended only to send a message that a person's LGBTQ identity is not recognized and LGBTQ people can be subjected to discrimination.

23. The Revised Rule's cost-benefit analysis is fatally flawed, incomplete, and unreasonable. Specifically, HHS fails to account for the increased costs to patients, insurers, and the health care system at large stemming from discrimination against LGBTQ and other patients.

24. The Revised Rule, if allowed to go into effect, will undermine the progress achieved so far in eradicating health care discrimination against LGBTQ people in a broad array of health care programs and entities by inviting health care insurers and providers once again to discriminate against them, while also discouraging LGBTQ people from seeking health care in the first instance.

25. In adopting the Revised Rule, HHS acted arbitrarily and capriciously, in excess of its statutory authority, and not in accordance with the law in violation of the Administrative Procedure Act ("APA") (5 U.S.C. § 551 *et seq.*). The Revised Rule also violates the Equal Protection Guarantee and Due Process Clause of the Fifth Amendment, and the Free Speech and Establishment Clauses of the First Amendment to the United States Constitution.

26. The Revised Rule is causing and will continue to cause irreparable harm to LGBTQ people and health care providers. The Revised Rule should be declared unlawful, enjoined, and vacated.

JURISDICTION AND VENUE

27. This Court has jurisdiction pursuant to 28 U.S.C. § 1331, as this action arises under the laws of the United States and United States Constitution; 28 U.S.C. § 1346, as a civil action against the United States founded upon the Constitution, an Act of Congress, or an

executive regulation; and 28 U.S.C. § 1361, as an action to compel an officer or agency to perform a duty owed to plaintiffs.

28. Jurisdiction also is proper under the Administrative Procedure Act, 5 U.S.C. §§ 701-706. Defendants' issuance of the Revised Rule on June 19, 2020, constitutes a final agency action that is subject to judicial review under 5 U.S.C. §§ 702, 704, and 706.

29. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory, injunctive, and other relief pursuant to 28 U.S.C. §§ 2201-2202 and 5 U.S.C. §§ 705-706.

30. Venue is proper in this district under 28 U.S.C. § 1391(b)(1), (b)(2), & (e)(1) because at least one plaintiff resides in this judicial district, a substantial part of the events or omissions giving rise to this action occurred in this district, and each defendant is an agency of the United States or an officer of the United States sued in their official capacity.

PARTIES

A. Plaintiffs

31. Plaintiffs are two private health care facilities that provide health care services to LGBTQ people and many individuals and families with LEP (Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health and the Los Angeles LGBT Center) ("private health care provider plaintiffs"); two organizations that provide a wide range of services to the LGBTQ community, including people and families with LEP (the TransLatin@ Coalition and Bradbury-Sullivan LGBT Community Center) ("LGBTQ-services plaintiffs"); two national associations of health professionals (American Association of Physicians for Human Rights d/b/a GLMA: Health Professionals Advancing LGBTQ Equality and AGLP: The Association of LGBTQ Psychiatrists) ("health professional association plaintiffs"); and three individual physicians and

one behavioral health provider who work for the private health care provider plaintiffs (“individual provider plaintiffs”).

32. The private health care provider plaintiffs (Whitman-Walker Health and the Los Angeles LGBT Center) and the individual provider plaintiffs assert claims on their own behalf and also on behalf of their patients and recipients of services, who face barriers to asserting their own claims and protecting their own interests.

33. The LGBTQ-services plaintiffs (the TransLatin@ Coalition and the Bradbury-Sullivan LGBT Community Center) assert claims on their own behalf and also on behalf of the recipients of their services who face barriers to asserting their own claims and protecting their own interests.

34. The TransLatin@ Coalition also asserts claims on behalf of its transgender and gender nonconforming members, including members who are leaders of affiliated community organizations serving Latinx transgender and gender nonconforming people.

35. The health professional association plaintiffs (GLMA and AGLP) assert claims on their own behalf and on behalf of their members and also on behalf of the LGBTQ patients whose interests they represent and the patients whom their members treat who face barriers to asserting their own claims and protecting their own interests.

36. Plaintiffs assert different but complementary interests and share the common objective of maintaining an effective, functioning health care system that protects patients’ dignity and their rights to access health services. Plaintiffs also support providing informed access to comprehensive, medically appropriate care to LGBTQ patients, including gender-affirming care for transgender persons, without discrimination based on a patient’s sex, gender

identity, transgender status, or sexual orientation and in accordance with medical and ethical standards of care.

37. Plaintiff **Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health**, a Federally Qualified Health Center located in Washington, D.C., has a special mission to serve the LGBTQ community and persons living with HIV of every sexual orientation and gender. More than 280 medical, behavioral health and dental professionals, lawyers and paralegals, support staff and administrators provide a range of services, including medical and community health care, transgender care and services, behavioral-health services, dental-health services, legal services, insurance-navigation services, and youth and family support. In 2019, Whitman-Walker provided health care services to 20,760 individuals. More than 10% of those individuals identified as transgender or gender nonconforming. Almost 45% of health care patients – and 60% of those who provided information on their sexual orientation – identified as lesbian, gay, bisexual, or otherwise non-heterosexual. More than 9% of patients had limited English proficiency. Whitman-Walker receives various forms of federal funding from HHS and from institutions affiliated with or funded by HHS, including but not limited to funds under the Public Health Services Act (“PHSA”), direct grants, funding under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, 42 U.S.C. § 300ff *et seq.* (“Ryan White funding”), funds under the 340B Drug Discount Program, and research grants from the Centers for Disease Control and Prevention and the National Institutes of Health, and Medicaid and Medicare reimbursements. Whitman-Walker also receives funds from the Health Resources and Service Administration (“HRSA”) and is a Federally Qualified Health Center. In 2019, Whitman-Walker’s federally funded research contracts and grants totaled more than \$7 million. Whitman-Walker is subject to Section 1557 of the ACA and the Revised Rule.

38. Plaintiff **Dr. Sarah Henn** is the Chief Health Officer of Whitman-Walker. Dr. Henn oversees all health care-related services at Whitman-Walker and maintains a panel of patients for whom she provides direct care. Whitman-Walker's patient population, including patients to whom Dr. Henn provides direct care and whose care she oversees, includes many patients who have experienced refusals of health care or who have been subjected to disapproval, disrespect, or hostility from medical providers outside of Whitman-Walker because of their actual or perceived sexual orientation, gender identity, or transgender status. Many of Dr. Henn's patients and those whose care she oversees are, therefore, apprehensive or fearful of encountering stigma and discrimination in health care settings because of their past experiences. Such experiences will increase as a result of the Revised Rule. In addition to overseeing medical care of patients and working with her own patients, Dr. Henn oversees Whitman-Walker's Research Department and is personally involved in a number of clinical research projects, including as the Leader of Whitman-Walker's Clinical Research Site for the AIDS Clinical Trials Group funded by the National Institutes of Health.

39. Plaintiff **Dr. Randy Pumphrey** is Senior Director of Behavioral Health at Whitman-Walker. As Senior Director of Behavioral Health, Dr. Pumphrey oversees Whitman-Walker's portfolio of mental-health services and substance-use-disorder-treatment services and maintains a panel of patients for whom he provides direct behavioral health care. In 2019, Whitman-Walker provided mental-health or substance-use-disorder-treatment services to more than 1,800 patients, many of whom identify as LGBT or are living with HIV. Many, if not most, of the patients to whom Dr. Pumphrey provides direct care and whose behavioral health care he oversees face considerable stigma and discrimination as people living with HIV, sexual or gender minorities, or people of color. They have experienced difficulty finding therapists or

other mental-health or substance-use-disorder professionals who are understanding and welcoming of their sexual orientation, gender identity, or transgender status. These experiences of discrimination will increase as a result of the Revised Rule.

40. Plaintiff **The TransLatin@ Coalition** is a nationwide 501(c)(3) nonprofit membership organization that advocates for the interests of transgender and gender nonconforming individuals, particularly Latinx people, and provides direct services to the transgender community, including leadership development, educational services, and employment services. The TransLatin@ Coalition currently has a presence in Los Angeles, California; Washington, D.C.; Chicago, Illinois; New York, New York; Atlanta, Georgia; Houston, Texas; and Tucson, Arizona. The TransLatin@ Coalition has thousands of individual members across the United States, including transgender and gender nonconforming Latinx individuals who have experienced or fear discrimination based on their sex, transgender status, national origin, or LEP status in health care. This includes individual transgender and gender nonconforming Latinx members like Bamby Salcedo, who resides in California, and Arianna Lint, who resides in Florida. Ms. Salcedo and Ms. Lint have experienced discrimination in health care because of their transgender status and fear the Revised Rule will make it more likely they will encounter discrimination in health care again. The TransLatin@ Coalition's membership also includes leaders of affiliated community organizations that serve Latinx transgender and gender nonconforming people across the country, such as Arianna's Center headquartered in Florida and with offices in Puerto Rico, Community Estrella in Georgia, and the Fundación Latinoamericana de Accion Social (FLAS) in Texas. The Coalition and its members advocate for policy changes at the local, state, and federal levels, and conducts research regarding homelessness, health and health care, and employment in the transgender Latinx

community. Through its Center for Violence Prevention & Transgender Wellness, the Coalition also provides direct services to transgender, gender nonconforming, and intersex people in the City of Los Angeles. Many of the members of the Coalition and the individuals they and the Coalition serve are immigrants, some living with HIV/AIDS. The Coalition and its members serve many communities in which English is not the primary language spoken and a number of individuals in these communities are not fluent in English.

41. Plaintiff **Los Angeles LGBT Center** is located in Los Angeles, California. Its mission is to build a world in which LGBT people thrive as healthy, equal, and complete members of society. The LA LGBT Center offers programs, services, and advocacy spanning four broad categories: health, social services and housing, culture and education, and leadership and advocacy. The LA LGBT Center has more than 750 employees and provides services to more LGBT people than any other organization in the world, with about 500,000 client visits per year, including LEP patients. LA LGBT Center receives funds under the PHSA. Approximately 80% of the LA LGBT Center's funding originates from the federal government, including but not limited to Ryan White funding; direct funding from the Centers for Disease Control and Prevention; discounts under the 340B Drug Discount Program; grants under section 330 of the PHSA; grants from HRSA's Bureau of Primary Health Care under which the LA LGBT Center is a Federally Qualified Health Center; and Medicaid and Medicare reimbursements. The LA LGBT Center is an entity subject to Section 1557 of the ACA and the Revised Rule.

42. Plaintiff **Dr. Robert Bolan** is the Chief Medical Officer of the LA LGBT Center. He oversees the delivery of health care for over 20,000 patients who come to the LA LGBT Center and personally treats approximately 300 patients. More than 90% of these patients identify as LGBT, many of them coming from different areas of California and other States to

obtain services in a safe and affirming environment. Dr. Bolan also oversees the LA LGBT Center's Research Department. Dr. Bolan and the providers he supervises treat patients who identify as transgender and who require gender-affirming treatment, including medically necessary health care for gender dysphoria. Many of Dr. Bolan's patients and many of the patients of the providers he supervises at the LA LGBT Center already have experienced traumatic and discriminatory denials of health care based on their sexual orientation, gender identity, transgender status, or HIV status at the hands of providers outside the LA LGBT Center, including by health care providers who have expressed religious or moral objections to treating them. These experiences will increase as a result of the Revised Rule.

43. Plaintiff **Dr. Ward Carpenter** is the Co-Director of Health Services at the LA LGBT Center. Dr. Carpenter is a nationally recognized expert in the field of transgender medicine. In his role as Co-Director of Health Services, Dr. Carpenter oversees the healthcare of more than 25,000 patients who come to the LA LGBT Center and personally treats 150 patients. All of Dr. Carpenter's patients identify within the LGBT community and approximately 30% are people living with HIV. These patients come from different areas of California and other States to obtain services in a safe and affirming environment. Dr. Carpenter's patient population is disproportionately low-income and experiences high rates of chronic medical conditions, homelessness, unstable housing, and extensive trauma history. In addition, many of Dr. Carpenter's patients, as well as the patients of the other medical providers he supervises at the Center, already have experienced traumatic and discriminatory denials of healthcare based on their sexual orientation, gender identity, transgender status, or HIV status at the hands of providers outside the LA LGBT Center, including by healthcare providers who have expressed

religious or moral objections to treating them. These experiences will increase as a result of the Revised Rule.

44. Plaintiff **Bradbury-Sullivan LGBT Community Center** is a 501(c)(3) nonprofit organization based in Allentown, Pennsylvania, and incorporated in Pennsylvania. It is dedicated to securing the health and well-being of LGBTQ people of the Greater Lehigh Valley. It provides a variety of programs and services for the LGBTQ community, including HIV/STI testing, health care-enrollment events, health promotion programs for LGBTQ adults and youth, support groups, and a free legal clinic. Bradbury-Sullivan Center also provides referrals to LGBT-welcoming health care providers. Patrons of Bradbury-Sullivan Center often seek health care services from other health care organizations, including religiously affiliated organizations. Bradbury-Sullivan Center works with patrons who have experienced discriminatory treatment when seeking health care services from such organizations, and it advocates on behalf of those patrons by providing referrals to LGBT-welcoming agencies and providers, training agencies to provide LGBT-welcoming services, and, when necessary, communicating with agencies to inform them of their legal obligations to serve LGBT people. Bradbury-Sullivan Center also conducts research documenting health disparities in the LGBT community and performs related community-education efforts to improve public health within the LGBT community. Bradbury-Sullivan Center receives pass-through funding from HHS through the Assistance Programs for Chronic Disease Prevention and Control, State Public Health Approaches to Ensuring Quitline Capacity funded in part by Prevention and Public Health Fund, State Physical Activity and Nutrition, Injury Prevention and Control Research and State and Community Based Programs, National State-Based Tobacco Control Programs, Maternal and Child Health Services Block Grant, and in the past also has received Ryan White funding.

45. Plaintiff **American Association of Physicians For Human Rights, Inc. d/b/a GLMA: Health Professionals Advancing LGBTQ Equality** (formerly known as the Gay & Lesbian Medical Association) is a 501(c)(3) nonprofit membership organization based in Washington, D.C. and incorporated in California. GLMA is a national organization committed to ensuring health equity for lesbian, gay, bisexual, transgender, queer, and all sexual and gender minority individuals, and equality for health professionals in such communities in their work and learning environments. To achieve this mission, GLMA utilizes the scientific expertise of its diverse multidisciplinary membership to inform and drive advocacy, education, and research. GLMA works with professional accreditation bodies and health professional associations on standards, guidelines, and policies that address LGBTQ health and protect individual patient health and public health in general. GLMA also represents the interests of hundreds of thousands of LGBTQ health professionals and millions of LGBTQ patients and families across the United States. GLMA's membership includes approximately 1,000 member physicians, nurses, advanced practice nurses, physician assistants, researchers and academics, behavioral health specialists, health-profession students, and other health professionals throughout the country. Their practices represent the major health care disciplines and a wide range of health specialties, including primary care, internal medicine, family practice, psychiatry, pediatrics, obstetrics/gynecology, emergency medicine, neurology, and infectious diseases.

46. Plaintiff **AGLP: The Association of LGBTQ Psychiatrists** is a 501(c)(3) nonprofit membership organization based in Philadelphia, Pennsylvania. AGLP is a national organization of 450 LGBTQ+ psychiatrists that educates and advocates on LGBTQ mental-health issues. It is the oldest association of LGBTQ+ professionals in the country. AGLP represents the interests of its members, LGBTQ+ patients, and the patients whom AGLP

members treat in working to influence policies relevant to the LGBTQ+ community and advocating for its members' patients. AGLP's goals are to foster a fuller understanding of LGBTQ+ mental-health issues; research and advocate for the best mental healthcare for the LGBTQ community; develop resources to promote LGBTQ mental health; create a welcoming, safe, nurturing, and accepting environment for members; and provide valuable and accessible services to our members. AGLP also assists medical students and residents in their professional development; encourages and facilitates the presentation of programs and publications relevant to LGBTQ concerns at professional meetings; and serves as liaison with other minority and advocacy groups within the psychiatric community. Some of the institutions in which AGLP's members work receive various forms of federal funding directly or indirectly via federal programs. AGLP's members therefore are subject to Section 1557 of the ACA and the Revised Rule.

B. Defendants

47. Defendant **United States Department of Health and Human Services** is a cabinet department of the federal government, headquartered in the District of Columbia. HHS promulgated the Revised Rule and is responsible for its enforcement. HHS is an "agency" within the meaning of the APA. 5 U.S.C. § 551(1).

48. Defendant **Alex M. Azar, II** is the Secretary of HHS. He is sued in his official capacity. Secretary Azar is responsible for all aspects of the operation and management of HHS, including the adoption, administration, and enforcement of the Revised Rule, and with implementing and fulfilling HHS's duties under the United States Constitution and the APA.

49. Defendant **Roger Severino** is the Director of the Office of Civil Rights ("OCR") at HHS. He is sued in his official capacity. Director Severino is responsible for all aspects of the operation and management of OCR, including the adoption, administration, and enforcement

of the Revised Rule. As an HHS law enforcement agency, OCR is supposed to ensure equal access to health and human services by enforcing civil rights laws such as Section 1557.

50. Defendant **Seema Verma** is the Administrator for the Centers for Medicare and Medicaid Services (“CMS”), a component of HHS. She is sued in her official capacity. Administrator Verma is responsible for all aspects of the operation and management of CMS, including the adoption, administration, and enforcement of the Revised Rule as it pertains to regulations relating to the establishment and operation of ACA exchanges; in the marketing and design practices of health insurance issuers under the ACA; in the administration, marketing, and enrollment practices of Qualified Health Plans (“QHPs”) under the ACA; in beneficiary enrollment and the promotion and delivery of services under Medicaid; and in the delivery of services under the Programs for All-Inclusive Care for the Elderly (“PACE”).

FACTUAL ALLEGATIONS

I. Discrimination Against Transgender People Prior to the Affordable Care Act

51. Before the Affordable Care Act was enacted in 2010 during the Obama Administration, HHS documented many forms of discrimination against transgender people in accessing health care services, insurance coverage, and facilities.

52. The administrative record documents and demonstrates that, prior to the enactment of the ACA, transgender people experienced significant discrimination from entities providing health care, even for routine medical care. HHS reported that “[f]or transgender individuals, a major barrier to receiving care is a concern over being refused medical treatment based on bias against them.” 81 Fed. Reg. 31,376, 31,460. For example, “[i]n a 2010 report, 26.7% of transgender respondents reported that they were refused needed health care. A 2011 survey revealed that 25% of transgender individuals reported being subject to harassment in medical settings.” *Id.*

53. Some entities providing insurance or health care discriminated against transgender patients by refusing to cover medically necessary treatments for gender dysphoria in accordance with accepted standards of care. Gender dysphoria is a serious medical condition codified in the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) and International Classification of Diseases (ICD-11). The criteria for diagnosing gender dysphoria are set forth in the DSM-V (302.85). The World Professional Association for Transgender Health (“WPATH”) publishes widely accepted standards of care for treating gender dysphoria. Leading medical organizations and federal courts have recognized the WPATH Standards of Care as the authoritative standards of care. The overwhelming consensus among medical experts and every major medical organization is that treatments for gender dysphoria, including surgical procedures, are effective, safe, and medically necessary when clinically indicated to alleviate gender dysphoria.

54. Prior to the enactment of the ACA, however, insurance companies routinely excluded coverage for transition-related care based on the misguided assumption that such treatments were cosmetic and experimental. Today, medical consensus recognizes that such exclusions have no basis in medical science.⁶

55. Those discriminatory exclusions prevented transgender people from obtaining medically necessary treatment for gender dysphoria. *See* 81 Fed. Reg. at 31,460. As a result, transgender people were more likely to lack health insurance and suffer significant health disparities, including high rates of untreated mental health needs, suicide attempts, and HIV. *Id.*

⁶ *See* Decision No. 2576, National Coverage Determination 140.3: Transsexual Surgery at 18 (Docket No. A-13-87) (U.S. Dep’t of Health & Human Servs. Appeals Bd. App. Div. 2014), <https://perma.cc/3BGA-F9DH>.

II. Section 1557 of the Affordable Care Act

56. On March 23, 2010, Congress enacted the Patient Protection and Affordable Care Act (“ACA”), Pub. L. No. 111-148, 124 Stat. 119 (2010), recognizing the importance of providing patients with prompt and nondiscriminatory access to medical care and to information about all treatment options.

57. Section 1554 of the ACA provides:

Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that—

- (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
- (2) impedes timely access to healthcare services;
- (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
- (4) restricts the ability of healthcare providers to provide full disclosure of all relevant information to patients making healthcare decisions;
- (5) violates the principles of informed consent and the ethical standards of healthcare professionals; or
- (6) limits the availability of healthcare treatment for the full duration of a patient’s medical needs.

42 U.S.C. § 18114.

58. Section 1557 of the ACA protects against discrimination in the provision of health care services. It provides, in relevant part:

Except as otherwise provided for in this title [I] (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of Title 29 [Section 504 of the Rehabilitation Act of 1973], be excluded from participation in, be denied the

benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title [I] (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.

42 U.S.C. § 18116(a).

59. Section 1557 prohibits discrimination based on sex, including discrimination based on a patient’s gender identity, transgender status, sexual orientation, and failure to conform to sex stereotypes, all of which are forms of sex discrimination. It also prohibits discrimination on the basis of race, color, national origin, age, and disability.

60. Section 1557 provides that “[t]he enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.” *Id.* § 18116(a).

61. Section 1557 further provides that the Secretary of HHS “may promulgate regulations to implement this section.” *Id.* § 18116(c).

62. The ACA covers nearly every health care provider in the country.

III. The 2016 Final Rule

63. On May 18, 2016, HHS published a final rule implementing Section 1557. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (May 18, 2016) (formerly codified at 45 C.F.R. pt. 92) (the “2016 Final Rule”). A copy of the 2016 Final Rule is attached as **Exhibit 1**.

64. In implementing Section 1557’s prohibition of discrimination “on the basis of . . . sex,” the 2016 Final Rule defined “on the basis of sex” to include “discrimination on the basis of

. . . sex stereotyping, and gender identity.” 81 Fed. Reg. at 31,467 (formerly codified at 45 C.F.R. § 92.4).⁷

65. The 2016 Final Rule defined “gender identity” as “an individual’s internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual’s sex assigned at birth.” *Id.* In the 2016 Final Rule, HHS emphasized that “even where it is permissible to make sex-based distinctions, individuals may not be excluded from health programs and activities for which they are otherwise eligible based on their gender identity.” 81 Fed. Reg. at 31,409.

66. The 2016 Final Rule defined “sex stereotypes” as

stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. These stereotypes can include the expectation that individuals will consistently identify with only one gender and that they will act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes also include gendered expectations related to the appropriate roles of a certain sex.

81 Fed. Reg. at 31,468 (formerly codified at 45 C.F.R. § 92.4).

67. In defining “on the basis of sex” to include “discrimination on the basis of . . . sex stereotyping, and gender identity,” HHS explained that “courts, including in the context of Section 1557, have recognized that sex discrimination includes discrimination based on gender

⁷ Although OCR stated in 2016 “that current law is mixed on whether existing Federal nondiscrimination laws prohibit discrimination on the basis of sexual orientation as a part of their prohibitions on sex discrimination,” 81 Fed. Reg. at 31388, the Supreme Court now has definitively answered this question by holding in *Bostock* that “it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex.” 2020 WL 3146686, at *7.

identity. Thus, we proposed to adopt formally this well-accepted interpretation of discrimination ‘on the basis of sex.’” 81 Fed. Reg. at 31,387-88.

68. The 2016 Final Rule also prohibited discrimination based on association – that is, it prohibited discrimination against a person on the basis of the sex, race, color, national origin, age, or disability of “an individual with whom the individual or entity is known or believed to have a relationship or association.” 81 Fed. Reg. at 31,472 (formerly codified at 92 C.F.R. § 209). HHS explained that a “prohibition on associational discrimination is consistent with longstanding interpretations of existing antidiscrimination laws, whether the basis of discrimination is a characteristic of the harmed individual or an individual who is associated with the harmed individual.” 81 Fed. Reg. at 31,439. It also is consistent with the Age Discrimination Act, which includes a specific prohibition of discrimination based on association with an individual with a disability. *Id.*; *see also* 42 U.S.C. § 12182(b)(1)(E); 28 C.F.R. § 35.130(g).

69. The 2016 Final Rule also recognized that Section 1557 not only prohibits intentional discrimination on the basis of sex, it also prohibits conduct and practices “that *have the effect of subjecting individuals to discrimination* on the basis of sex,” which can give rise to disparate impact claims. 81 Fed. Reg. at 31,470 (formerly codified at 45 C.F.R. § 92.101(b)(3)(ii)) (emphasis added).

70. The 2016 Final Rule applied to “every health program or activity, any part of which receives Federal financial assistance provided or made available by the Department; every health program or activity administered by the Department; and every health program or activity administered by a Title I entity.” 81 Fed. Reg. at 31,466 (formerly codified at 45 C.F.R.

§ 92.2(a)). HHS estimated that the rule would “likely cover almost all licensed physicians because they accept Federal financial assistance.” 81 Fed. Reg. at 31,445.

71. With respect to health care insurance providers or employee benefits plans, the 2016 Final Rule specifically required covered entities to treat individuals consistent with their gender identity. *See* 81 Fed. Reg. at 31,471 (formerly codified at 45 C.F.R. § 92.206). And it prohibited covered entities from having or implementing “a categorical coverage exclusion or limitation for all health care services related to gender transition,” 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.207(b)(4)), because such an exclusion is “discriminatory on its face,” 81 Fed. Reg. at 31,456. In adopting these provisions, HHS explained that blanket “exclusions of coverage for all care related to gender dysphoria or associated with gender transition” were “outdated and not based on current standards of care.” 81 Fed. Reg. at 31,429.

72. The “range of transition-related services” the 2016 Final Rule contemplated were “not limited to surgical treatments and may include, but [were] not limited to, services such as hormone therapy and psychotherapy, which may occur over the lifetime of the individual.” 81 Fed. Reg. at 31,435-36.

73. Consistent with the plain language of Section 1557, which provides that the “enforcement mechanisms provided for and available under such title VI, title IX, section 794, *or* such Age Discrimination Act shall apply for purposes of violations” of Section 1557, 42 U.S.C. § 18116(a) (emphasis added), the 2016 Final Rule adopted a unitary legal standard for addressing discrimination in health care and enforcing Section 1157. The 2016 Final Rule provided: “The enforcement mechanisms available for and provided under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, *or* the Age Discrimination Act of 1975 shall apply for purposes of

Section 1557 as implemented by this part.” 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.301) (emphasis added).

74. In the preamble to the 2016 Final Rule, HHS clarified that *all* enforcement mechanisms available under the statutes listed in Section 1557 are available for purposes of Section 1557 enforcement, regardless of an individual’s protected characteristic or characteristics. Otherwise, different enforcement mechanisms and standards would apply depending on whether an individual’s claim is based on her sex, race, age, or disability. 81 Fed. Reg. at 31,439-40. HHS thus interpreted Section 1557 as “authorizing a private right of action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation.” *Id.* at 31,440.

75. The 2016 Final Rule also specifically recognized that a private right of action is available under Section 1557 and compensatory damages are available. *See* 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. §§ 92.301(b), 92.302(d)). HHS explained that its “interpretation of Section 1557 as authorizing compensatory damages is consistent with our interpretations of Title VI, Section 504, and Title IX.” 81 Fed. Reg. at 31,440.

76. The 2016 Final Rule did not incorporate Title IX’s blanket religious exemption because Section 1557 “contains no religious exemption.” 81 Fed. Reg. at 31,380. In declining to import Title IX’s religious exemption, HHS further explained that “Title IX and its exemption are limited in scope to educational institutions, and there are significant differences between the educational and health care contexts that warrant different approaches.” *Id.* HHS noted that “a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results.” *Id.*

77. After a careful and deliberate analysis, HHS determined that a “more nuanced approach in the health care context” was warranted. *Id.* The 2016 Final Rule provided: “Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required.” 81 Fed. Reg. at 31,466 (formerly codified at 45 C.F.R. § 92.2(b)(2)).

78. The 2016 Final Rule also included provisions to ensure that the approximately 25 million Americans who are Limited English Proficient (LEP)⁸ have access to the health care they need. The 2016 Final Rule required health care providers and other covered entities to post nondiscrimination notices and include taglines in the top 15 languages spoken throughout the state with all significant publications and communications. *See* 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.8).

79. The 2016 Final Rule also included standards that governed access to language assistance services for LEP individuals by requiring that language interpreters be “qualified” and that when covered entities video interpretation services to LEP individuals, it be real-time and high quality. *See* 81 Fed. Reg. at 31,470-71 (formerly codified at 45 C.F.R. § 92.201).

80. The promulgation of the 2016 Final Rule led to a decrease in discriminatory policies and practices.⁹ For example, a recent study of 37 states in the federal marketplace

⁸ U.S. Census Bureau, *Language Spoken at Home*, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1601 (2018), <https://perma.cc/Z452-RSWR>; U.S. Census Bureau, *Characteristics of People by Language Spoken at Home*, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1603, <https://perma.cc/R59J-HG4K>.

⁹ *See* Gruberg & Bewkes, *The ACA’s LGBTQ Nondiscrimination Regulations Prove Crucial*, <https://perma.cc/CTP2-UMEJ>.

showed that, in 2019, 97% of plans did not contain blanket exclusions of transition-related care.¹⁰

IV. The Trump Administration’s Proposed Revision to the 2016 Final Rule

81. On June 14, 2019, the Trump Administration issued a Notice of Proposed Rulemaking, proposing to “make substantial revisions” to the 2016 Final Rule, including repealing certain provisions. *See* Notice of Proposed Rulemaking, *Nondiscrimination in Health and Health Education Programs or Activities*, 84 Fed. Reg. 27,846, 27,848 (June 14, 2019) (“Proposed Rule”).

82. In an attempt to explain why it was reversing course merely three years after the 2016 Final Rule went into effect, HHS stated it was revising the implementing regulations “to better comply with the mandates of Congress, address legal concerns, relieve billions of dollars in undue regulatory burdens, further substantive compliance, reduce confusion, and clarify the scope of Section 1557 in keeping with existing civil rights statutes and regulations prohibiting discrimination on the basis of race, color, national origin, sex, age, and disability.” 84 Fed. Reg. at 27,846.

83. HHS further claimed that the 2016 Final Rule “exceeded its authority under Section 1557, adopted erroneous and inconsistent interpretations of civil rights law, caused confusion, and imposed unjustified and unnecessary costs.” *Id.* at 27,849.

84. These purported justifications do not withstand scrutiny.

85. HHS received nearly 200,000 comments during the public comment period. The comments that HHS received identified and expressed concerns about many of HHS’s proposed

¹⁰ Out2Enroll, *Summary of Findings: 2020 Marketplace Plan Compliance with Section 1557*, <https://perma.cc/WU25-C9BN>. This finding is consistent with summaries from 2017, 2018, and 2019.

revisions, including many of the same issues that form the basis of this complaint. Commenters emphasized that the following actions, taken individually or combined, will cause immediate and irreparable harm to LGBTQ people and their families:

- a. Eliminating the definition of “on the basis of sex” and the specific prohibition on discrimination on the basis of gender identity and sex stereotyping is arbitrary and capricious, not the result of reasoned decision-making, contrary to law, and invites covered health care providers and insurers to discriminate against transgender people;
- b. Eliminating a unitary legal standard for enforcing violations of Section 1557 and replacing it with a fractured and complex set of procedures is contrary to the plain language of Section 1557 and Congress’s intent, and will complicate and make it more difficult to bring discrimination claims, particularly claims of intersectional discrimination;
- c. Incorporating sweeping religious exemptions is contrary to the statutory language of Section 1557 and will create significant burdens on patients and providers;
- d. Eliminating notice requirements and critical language access provisions that ensure LEP individuals can access necessary health care is arbitrary and capricious, contrary to statutory intent, and will make it more difficult for LEP patients to understand their health care rights, communicate with doctors and other health care workers, and navigate complex insurance and medical documents with specialized terminology, and cause an increase in patients who will delay or not seek care at all;

- e. Excluding from Section 1557 health programs and activities that HHS administers but are not established under Title I of the ACA and health insurance plans outside of Title I of the ACA that do not receive Federal financial assistance is inconsistent with Section 1557 and will cause drastic reductions in protections for LGBTQ people;
- f. Eliminating gender identity and sexual orientation protections in unrelated regulations is procedurally improper, arbitrary and capricious, and contrary to law; and
- g. Eliminating protections relating to discrimination on the basis of association is arbitrary and capricious and contrary to law.

V. The Revised Rule

86. Despite the significant concerns raised during the comment period, HHS published the Revised Rule in the Federal Register on June 19, 2020, making only “minor and primarily technical corrections.” *See* Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160, 37,161 (June 19, 2020). A copy of the Revised Rule is attached as **Exhibit 2** and incorporated by reference.

87. In adopting the Revised Rule, HHS failed to address adequately many of the serious issues commenters raised, including concerns that the proposed elimination of the definition of “on the basis of sex,” which the 2016 Final Rule defined to include gender identity and sex stereotyping, would invite discrimination against LGBTQ people. *See* 85 Fed. Reg. at 37,165, 37,180.

88. Relying essentially on one federal district court opinion—*Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016)—which the preamble cites more than 40 times, HHS takes the position that “the ordinary public meaning of the term ‘sex’ in Title IX is

unambiguous” and refers to a “biological binary meaning of sex,” 85 Fed. Reg. at 37,178-80, and discrimination on the basis of sex under Title IX does not encompass discrimination on the basis of gender identity or sex stereotyping, 85 Fed. Reg. at 37,183-86.

89. HHS explicitly rejected comments urging it to wait until the Supreme Court decided *Bostock* and related cases because of the potential implications for the Revised Rule. *See* 85 Fed. Reg. at 37,168. Despite acknowledging that “a holding by the U.S. Supreme Court on the meaning of ‘on the basis of sex’ under Title VII will likely have ramifications for the definition of ‘on the basis of sex’ under Title IX,” because “Title VII case law has often informed Title IX case law with respect to the meaning of discrimination ‘on the basis of sex,’” *id.*, HHS stated it was sticking with the position the federal government had taken in *Bostock* and related cases that “discrimination ‘on the basis of sex’ in Title VII and Title IX does not encompass discrimination on the basis of sexual orientation or gender identity,” *id.*

90. HHS further asserted that even if the Supreme Court determined that the prohibition on sex discrimination in Title VII encompassed gender identity and sexual orientation, such a ruling may not fully address the implications for the health care context. 85 Fed. Reg. at 37,168.

91. Among other revisions, the Revised Rule:

- a. Repeals the definition of “on the basis of sex” and the specific prohibition of discrimination on the basis of gender identity and sex stereotyping, *see* 85 Fed. Reg. at 37,161-62;
- b. Repeals the unitary legal standard for enforcing violations of Section 1557 and eliminates provisions recognizing a private right of action and compensatory damages, *see* 85 Fed. Reg. at 37,162;

- c. Incorporates sweeping religious exemptions, *see id.*;
- d. Repeals notice requirements and access to language provisions, *see id.*;
- e. Excludes from the scope of Section 1557 certain health programs and activities and health insurance plans, *see id.*;
- f. Repeals gender identity and sexual orientation protections in unrelated regulations, *see id.*; and
- g. Repeals provisions relating to discrimination on the basis of association, *see id.*

92. These changes are arbitrary and capricious, not the process of reasoned decision-making, contrary to the statutory language and Congress’s intent, not in accordance with law, in excess of HHS’s statutory authority, and unconstitutional.

VI. HHS’s Repeal of the Definition of “On the Basis of Sex” and Protections Against Discrimination on the Basis of Gender Identity and Sex Stereotyping Is Arbitrary and Capricious and Contrary to Law

93. Section 1557 prohibits sex discrimination. In line with that prohibition, the 2016 Final Rule included a definition of “on the basis of sex” that explicitly prohibited discrimination on the basis of gender identity and sex stereotyping, among other grounds. *See* 81 Fed. Reg. at 31,467 (formerly codified at 45 C.F.R. § 92.4).

94. The Revised Rule repeals entirely the 2016 Final Rule’s definition of discrimination “on the basis of sex,” without providing a different definition. Although HHS’s Notice of Proposed Rulemaking stated HHS was declining to define the term because “of the likelihood that the Supreme Court will be addressing the issue in the near future,” 84 Fed. Reg. at 27,857, HHS did not wait for the Supreme Court to decide whether discrimination on the basis of “sex” encompasses discrimination against LGBTQ people.

95. Instead, it staked its elimination of the definition of “on the basis of sex” on the *Franciscan Alliance* decision and the government’s position in the *Bostock* litigation “that discrimination ‘on the basis of sex’ in Title VII and Title IX does not encompass discrimination on the basis of sexual orientation or gender identity.” 85 Fed. Reg. at 37,168.

96. The Supreme Court now has conclusively rejected that position, holding “it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual on the basis of sex.” *Bostock*, 2020 WL 3146686, at *7. *Bostock*’s conclusion that discrimination “on the basis of sex” encompasses claims of discrimination based on transgender status and sexual orientation affirms the validity of the substantial body of case law that formed the basis of the 2016 Final Rule. *See* 81 Fed. Reg. at 31,387-90, 31,392.

97. The Revised Rule’s repeal of the definition of “on the basis of sex” and elimination of the protections for LGTBQ people against discrimination is contrary to law and will invite health care insurers and providers to discriminate against LGBTQ people seeking health care. It also introduces substantial confusion among health care providers and insurers regarding their legal obligations and the right of the populations they serve to be free from discrimination, particularly in light of the Supreme Court’s ruling in *Bostock*.

98. The Revised Rule also eliminates the provisions in the 2016 Final Rule specifically requiring covered entities to treat individuals consistent with their gender identity and prohibiting covered entities from having or implementing “a categorical coverage exclusion or limitation for all health care services related to gender transition.” *Compare* 81 Fed. Reg. at 31,471-72 (formerly codified at 45 C.F.R. §§ 92.101(b)(3)-(4)), *with* 85 Fed. Reg. at 37,187-88.

99. HHS claims this provision inappropriately interfered with the ethical and medical judgment of health professionals. *See* 85 Fed. Reg. at 37,187-88. However, as the 2016 Final Rule demonstrates, prohibiting the exclusion or denial of health programs or activities on the basis of an individual's LGBTQ status does not prevent medical providers from providing appropriate medical advice.

100. The Revised Rule also eliminates the provision in the 2016 Final Rule that prohibited a covered entity from discriminating against an individual based on those with whom they are known or believed to have a relationship or to be associated. *Compare* 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.209), *with* 85 Fed. Reg. at 37,199-200. The 2016 Final Rule grounded this provision on a thorough examination of existing case law. *See* 81 Fed. Reg. at 31,438-39.

101. Former Section 92.209 accurately reflected current law. HHS has provided no good reason to eliminate it. Its decision to do so is arbitrary and capricious and contrary to the law, in violation of the APA.

VII. The Revised Rule's Repeal of the Unitary Standard Is Arbitrary and Capricious and Contrary to Law

102. Section 1557 provides: "The enforcement mechanisms provided for and available under such title VI, title IX, section 794, *or* such Age Discrimination Act shall apply for purposes of violations of [Section 1557]." 42 U.S.C. § 18116(a) (emphasis added). Congress's use of the disjunctive "or" indicates that the enforcement mechanisms applicable under any of the incorporated statutes are available to every claim of discrimination under Section 1557, regardless of the particular type of discrimination.

103. During the notice-and-comment period on the 2016 Final Rule, commenters pointed to the plain language of Section 1557 and asked HHS to "clarify that all enforcement

mechanisms available under the statutes listed in Section 1557 are available to each Section 1557 plaintiff, regardless of the plaintiff's protected class. Thus, for example, an individual could bring a race claim under the Age Act procedure and an age claim under the Title VI procedure.” 81 Fed. Reg. at 31,439.

104. As commenters emphasized, by enacting Section 1557, Congress intended to create a new health-specific, anti-discrimination cause of action subject to a singular standard regardless of a person's protected characteristic. Otherwise, different enforcement mechanisms and standards would apply depending on whether an individual's claim is based on their sex, race, national origin, age, or disability, in which case a person who faces intersectional discrimination – that is, discrimination based on more than one ground – would have different remedies and enforcement mechanisms for the same conduct under the same law. *Id.* at 31,439-40.

105. In response, HHS stated: “OCR interprets Section 1557 as authorizing a private right of action for claims of disparate impact on the basis of any of the criteria enumerated in the legislation.” *Id.* at 31,440.

106. The 2016 Final Rule specified, consistent with this interpretation, that Section 1557 not only prohibits intentional discrimination on the basis of sex, but also conduct and practices “that *have the effect of subjecting individuals to discrimination* on the basis of sex” – conduct that can give rise to disparate impact claims based on sex. 81 Fed. Reg. at 31,470 (formerly codified at 45 C.F.R. § 92.101(b)(3)(ii)) (emphasis added).

107. The 2016 Final Rule implemented Section 1557's directives regarding enforcement by promulgating 45 C.F.R. § 92.301, which provided: “The enforcement mechanisms available for and provided under Title VI of the Civil Rights Act of 1964, Title IX

of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, *or* the Age Discrimination Act of 1975 shall apply for purposes of Section 1557 as interpreted by this part.” 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.301(a)) (emphasis added).

108. In addition, the 2016 Final Rule specified that a private right of action is available under Section 1557 and compensatory damages are available. *See* 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. §§ 92.301(b), 92.302(d)). HHS explained that its “interpretation of Section 1557 as authorizing compensatory damages is consistent with our interpretations of Title VI, Section 504, and Title IX.” 81 Fed. Reg. at 31,440.

109. Under these regulations, individuals bringing claims of intersectional discrimination, i.e., discrimination based on multiple characteristics, would not need to litigate their claims under different standards and different enforcement mechanisms.

110. The Revised Rule, however, without reasoned explanation, rejects the 2016 Final Rule’s establishment of a unitary legal standard and enforcement mechanism under Section 1557, limiting the remedies available from claims of discrimination based on a characteristic listed in Section 1557 to only those remedies available under the statute from which the characteristic was incorporated. HHS acknowledged commenters raised concerns about intersectional discrimination but brushed them aside by noting that OCR accepts complaints that allege discrimination based on more than one protected status. 85 Fed. Reg. at 37,199-200.

111. HHS claims the 2016 Final Rule applied the enforcement mechanisms in existing statutes “in a confusing and inconsistent manner,” 85 Fed. Reg. at 37,202, and resulted in “a new patchwork regulatory framework unique to Section 1557 covered entities,” 85 Fed. Reg. at 37,162.

112. The 2016 Final Rule accomplished precisely the opposite. It established a consistent, unitary legal standard and enforcement mechanism as Section 1557 contemplates. It is HHS’s arbitrary and capricious elimination of a unitary standard that creates a confusing and patchwork approach, applying different remedies and enforcement mechanisms to discriminatory conduct that arises under a single statute – Section 1557.

113. The Revised Rule also eliminates, without providing a reasoned explanation, the provisions in the 2016 Final Rule expressly recognizing a private right of action to “challenge a violation of Section 1557 or this part.” *Compare* 81 Fed. Reg. at 31,472 (formerly codified 45 C.F.R. § 92.302(d)), *with* 85 Fed. Reg. at 37,203.

114. HHS eliminated the private right of action provision even though the existence of such a right is clear from the statutory language of Section 1557, which explicitly references and incorporates the “enforcement mechanisms” of four civil rights laws, all of which have a private right action, and even though every court that has ruled on the question has held that the statutory language of Section 1557 confers a private right of action.

115. The Revised Rule also eliminates, without providing a reasoned explanation, § 92.301(b) of the 2016 Final Rule that recognized “[c]ompensatory damages for violations of Section 1557 are available in appropriate administrative and judicial actions brought under this rule.” 81 Fed. Reg. at 31,472 (formerly codified 45 C.F.R. § 301(b)). The only justification HHS offers is that “the Department has concluded that its enforcement of Section 1557 should conform to the Department of Justice’s Title VI Manual,” which states that “under applicable Federal case law, compensatory damages are generally unavailable for claims based solely on a Federal agency’s disparate impact regulations.” 85 Fed. Reg. at 37,202.

116. HHS ignores entirely its own statement in the preamble to the 2016 Final Rule that its interpretation of Section 1557 as authorizing compensatory damages was consistent with HHS’s “interpretations of Title VI, Section 504, and Title IX,” as providing for compensatory damages. *See* 81 Fed. Reg. at 31,440. HHS’s elimination of the provision recognizing the availability of compensatory damages also is inconsistent with controlling U.S. Supreme Court decisions holding that damages are available under these civil rights statutes.

117. HHS’s unreasonable interpretation of Section 1557 is arbitrary, capricious, and contrary to law in that it fails to follow the statutory language of Section 1557 and apply each of the “enforcement mechanisms” available under each of the civil rights statutes incorporated into Section 1557 to every claim of discrimination arising under Section 1557 regardless of the basis. HHS’s arbitrary and capricious elimination of provisions recognizing a private right of action under Section 1557 and the availability of compensatory damages likewise is contrary to the plain language of the statute and the law.

118. Although HHS cannot change the law, its fracturing of the consolidated procedures established in the 2016 Final Rule undermines Congress’s intent to create a new, health-specific anti-discrimination cause of action and will make it more difficult to bring discrimination claims under Section 1557. HHS’s elimination of the private right of action and compensatory damages provisions also will confuse the public and mislead some persons into not asserting their legal rights.

VIII. The Revised Rule’s Incorporation of Sweeping Religious Exemptions Conflicts with the Statutory Language of Section 1557 and Is Inappropriate in the Health Care Context

119. The 2016 Final Rule included a provision stating that covered entities do not have to comply with Section 1557 if doing so would violate applicable federal statutory protections

for religious conscience and freedom. *See* 81 Fed. Reg. at 31,466 (formerly codified at 45 C.F.R. § 92.2(b)(2)).

120. HHS considered incorporating Title IX’s blanket religious exemptions into Section 1557, but after careful consideration and deliberation, HHS declined to do so in the 2016 Final Rule. 81 Fed. Reg. at 31,379-80. Title IX’s religious exemption by its terms applies only to educational institutions and programs, not health care providers or health plans. It protects religiously-controlled educational institutions and programs from requirements that violate their religious tenets. *See* 20 U.S.C. § 1681(a)(3); 34 C.F.R. § 106.12. For example, religious schools that believe only men can be priests, rabbis, or ministers are not required to admit women to training programs for the priesthood, rabbinate, or ministry.

121. In declining to import Title IX’s blanket religious exemption into Section 1557, HHS explained that Section 1557, unlike Title IX, does not include a religious exemption. It further explained that Title IX’s blanket exemption would be inappropriate in the health care setting because it is framed for educational institutions, which are very different from health care settings, and those differences “warrant different approaches.” 81 Fed. Reg. at 31,380.

122. HHS noted that, unlike the educational context where individuals may select a religious educational institution by choice, in the health care context, individuals may have limited or no choice of providers. *Id.* In addition, “a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results.” *Id.*

123. HHS determined that a “more nuanced approach in the health care context” was warranted. *Id.* As a result, the 2016 Final Rule provided: “Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious

freedom and conscience, such application shall not be required.” 81 Fed. Reg. at 31,466 (formerly codified at 45 C.F.R. § 92.2(b)(2)).

124. The Revised Rule upends this nuanced and carefully considered approach by explicitly identifying and incorporating sweeping religious exemptions from a number of different statutes. Not only does the Revised Rule incorporate the Title IX religious exemptions, it also incorporates “definitions, exemptions, affirmative rights, or protections” from unrelated statutes. 85 Fed. Reg. at 37,245 (to be codified at 45 C.F.R. § 92.6(b)).

125. The inclusion of sweeping religious exemptions in Section 1557 is contrary to the statutory language of Section 1557, which by its terms does not incorporate any exemptions from Title IX or any other statute. Section 1557 expressly incorporates the enforcement mechanisms from four civil rights statutes, but pointedly does not incorporate the religious exemptions from Title IX or any other statute.

126. Religiously affiliated hospitals and health care systems occupy a large and growing percentage of health care markets. The Revised Rule’s sweeping religious exemptions to Section 1557’s prohibitions on discrimination will invite these institutions to allow their religious beliefs to determine patient care, contrary to medical standards and the health of an increasing number of individuals.

127. The Revised Rule also invites individual health care providers to deny care to LGBTQ patients on the basis of their individual religious beliefs. It prioritizes the protection of individual conscience and religious freedom rights over ensuring that LGBTQ people receive the health care to which they are entitled. *See* 85 Fed. Reg. at 37,206.

128. The Revised Rule’s religious exemptions disproportionately harm LGBTQ people, who often are refused health care because of their sexual orientation or gender identity.

According to a 2018 study, 8% of LGBTQ people were refused health care because of their sexual orientation, and 29% of transgender people were denied care because of their gender identity.¹¹

129. When LGBTQ people are denied care, it becomes difficult and sometimes impossible to find another provider, especially for those who live in rural areas and for transgender people. In one recent study, 18% of LGBTQ people said it would be very difficult if not impossible to find the same type of service in another hospital. Outside of a metropolitan area, 41% of respondents stated that, if they were denied treatment, it would be very difficult if not impossible to find the same service at a different location.¹²

130. These religious exemptions also will frustrate the ability of organizations who provide health care to LGBTQ patients to accomplish their missions. Individual health care providers employed by these organizations may choose to deny care to LGBTQ patients, claiming that doing so would violate their religious beliefs. This denial of care would harm the ability of these organizations to treat their patients effectively. These exemptions also would impair the ability of these organizations to refer their LGBTQ patients to other health care providers because they would be unsure whether these providers would invoke these exemptions to deny care to LGBTQ patients.

¹¹ Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People From Accessing Health Care*, Center for American Progress (Jan. 18, 2018), <https://perma.cc/ZG7E-7WK8>.

¹² *Id.*

IX. The Revised Rule's Elimination of Notices of Nondiscrimination Rights and Language Access Provisions Is Arbitrary and Capricious and Contrary to Statutory Intent

131. More than 25 million Americans are of LEP, meaning they speak, read, or write English less than “very well.”¹³ An estimated 6.5 million LEP adults are uninsured.¹⁴

132. The 2016 Final Rule contained a number of provisions to ensure that LEP patients understand their rights and are able to communicate fully and effectively with their providers and other health care staff. The 2016 Final Rule required covered entities to provide notice of nondiscrimination policies, including notice of availability of and how to access language assistance services. 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.8(a)).

133. In addition, covered entities were required to include taglines on all significant documents in the top fifteen languages spoken by individuals with LEP in their state. 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.8(d)(1)). Taglines are short statements that inform individuals of their right to language assistance and how to seek such assistance.

134. The 2016 Final Rule also required that a covered entity with at least 15 employees designate a specific individual or individuals with responsibility to oversee compliance with Section 1557, including LEP efforts, and investigate complaints and concerns and establish and adhere to a specific grievance procedure. 81 Fed. Reg. at 31,469 (formerly codified at 45 C.F.R. § 92.7).

¹³ See U.S. Census Bureau, *Language Spoken at Home*, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1601 (2018), <https://perma.cc/Z452-RSWR>; U.S. Census Bureau, *Characteristics of People by Language Spoken at Home*, American Community Survey 2018 1-Year Estimates Subject Tables, tbl. S1603, <https://perma.cc/R59J-HG4K>.

¹⁴ See Letter from Kathy Ko Chin, President & CEO, Asian & Pacific Islander American Health Forum, to Roger Severino, Dir., Office of Civil Rights, U.S. Dep't Health & Hum. Servs., at 21 (Aug. 13, 2019), <https://perma.cc/6HWW-6833>.

135. The Revised Rule repeals §§ 92.7 and 92.8 of the 2016 Final Rule, eliminating the notice and tagline requirements and the requirement to designate a specific individual to oversee Section 1557 compliance, including LEP efforts, and grievance procedure requirements. *See* 85 Fed. Reg. at 37,204.

136. The elimination of the notice, tagline, and LEP requirements is arbitrary and capricious and will result in some LEP patients failing to understand or assert their rights. It also will result in some LEP patients failing to receive adequate care because of the difficulties patients may have in understanding their providers or other staff, undermining the purpose and intent of the nondiscrimination provisions of Section 1557.

137. HHS has not explained how individuals will know about their rights and how elimination of notices will not deny LEP individuals meaningful access to health care.

X. The Revised Rule's Attempt to Narrow the Scope of Health Programs and Activities Subject to Section 1557 is Arbitrary and Capricious and Contrary to Law

138. The plain language of Section 1557 prohibits discrimination based on sex, race, color, national origin, age, and disability under:

any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under [Title I of the ACA] (or amendments).

42 U.S.C. § 18116(a).

139. The 2016 Final Rule correctly interpreted Section 1557 to cover all health-related operations and programs of any health care or health insurance provider, if any part of its operations receives Federal financial assistance; any other health program or activity that HHS administers; or any health insurance exchange or other entity established under ACA Title I or health insurance-exchange-related insurance plan.

140. The Revised Rule attempts to limit the scope of Section 1557 in two principal ways. First, it applies Section 1557's nondiscrimination protections only to health programs or activities of HHS that are administered under Title I of the ACA, not to other health programs and activities that HHS administers. 85 Fed. Reg. at 37,244 (to be codified at 45 C.F.R. § 92.3(a)(2)). Such a limitation excludes from Section 1557 numerous HHS health programs and activities, including health programs and activities of the Centers for Medicare and Medicaid Services, the Centers for Disease Control and Prevention, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.

141. The Revised Rule's interpretation of the scope of Section 1557 is inconsistent with and contradicts the plain language of Section 1557, which states that it applies to "any program or activity that is administered by an Executive Agency." 42 U.S.C. § 18116(a). It does not limit Section 1557 to health programs and activities established or administered under ACA Title I.

142. Second, the Revised Rule erroneously declares that health insurers are not a "health program or activity" under Section 1557 and not subject to Section 1557's nondiscrimination prohibitions because, now according to HHS, they are not "principally engaged in the business of providing healthcare." 85 Fed. Reg. at 37,244-45 (to be codified at 45 C.F.R. § 92.3(c)).

143. By declaring that health insurance providers are not principally engaged in the business of providing health care, HHS purports to exclude health insurance providers from the requirements of Section 1557, except for plans offered on the Health Insurance Marketplace or Federally-facilitated Marketplace created under Title I and insurance plans outside of Title I that receive Federal financial assistance. For those health insurers that operate plans outside of Title I

but receive Federal financial assistance, the Revised Rule further limits the application of Section 1557 to only those operations that receive Federal financial assistance—all other operations of the insurer are excluded. 85 Fed. Reg. at 37,244 (to be codified at 45 C.F.R. § 92.3(b)).

144. This Revised Rule exempts many plans, products, and operations of many health insurance issuers, such as self-funded group health plans, the Federal Employees Health Benefits (FEHB) Program, and short-term limited duration insurance plans. 85 Fed. Reg. at 37,173-74.

145. To support its new interpretation, HHS contends that providing “health insurance” is different than providing “healthcare” and points to the definitions of “healthcare” and “health insurance” in unrelated statutes to support its distinction. 85 Fed. Reg. at 37,172-73.

146. But Section 1557 covers “health programs and activities,” not just direct health care. Health insurance clearly is a health-related program or activity. It is what enables the vast majority of Americans to access health care. Indeed, health insurance companies design the health care individuals receive by determining benefits offered and establishing formularies, payment structures, and networks. They also conduct prior authorization and establish and evaluate other clinical coverage criteria, as well as exercise considerable control over the health care of enrollees—deciding which providers a patient may see, what hospitals they may visit, and what treatments or medications they may receive.

147. Neither the plain language of Section 1557 nor HHS’s effort to rely on unrelated statutes supports HHS’s unreasonable assertion that “healthcare” is different than “health insurance.” Section 1557 explicitly provides that it covers “health programs and activities.” Its scope is not limited to direct health care.

XI. The Revised Rule Arbitrarily and Capriciously Eliminates Gender Identity and Sexual Orientation Protections in Unrelated Regulations

148. The Revised Rule amends a series of unrelated regulations that had identified gender identity and sexual orientation as prohibited bases of discrimination, including regulations related to Medicaid State Plans, Programs for All-Inclusive Care for the Elderly (PACE), and ACA state health insurance exchanges and plans. The Revised Rule eliminates protections against gender identity and sexual orientation discrimination in those regulations. 85 Fed. Reg. at 37,218-22, 37,243.

149. These regulations were not issued pursuant to Section 1557 and do not interpret Section 1557. They were promulgated by CMS pursuant to the authority granted by several unrelated statutes. These unrelated regulations were not promulgated pursuant to HHS's authority to implement regulations under Section 1557.

150. For example, the Revised Rule amends regulations regarding Medicaid State Plans and Medicaid contractors, 42 C.F.R. §§ 438.3(d)(4), 438.206 (c)(2), and 440.262, which were issued pursuant to HHS's authority under Section 1902 of the Social Security Act to implement Section 1902(a)(19). That section directs HHS to "provide such safeguards as may be necessary to assure that eligibility for care and services under the [Medicaid] plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interest of the recipients." 42 U.S.C. § 1396a(a)(19); *see also* Medicaid and Children's Health Insurance Program (CHIP) Programs, 81 Fed. Reg. 27,498, 27,538-39, 27,666 (May 6, 2016).

151. Prior to the Revised Rule, 42 C.F.R. § 438.3(d)(4) provided: "The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, sexual orientation, gender identity, or disability and will

not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, sexual orientation, gender identity, or disability.” The Revised Rule amends § 438.3(d)(4) to state: “The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, or disability.” 85 Fed. Reg. at 37,243 (to be codified at 42 C.F.R. § 438.3(d)(4)).

152. PACE is a program for services for frail community-dwelling elderly persons, most of whom are Medicaid and Medicare dual eligible, to keep them in the community rather than moving to nursing homes. *See* 42 C.F.R. §§ 460.98, 460.112. HHS added sexual orientation to the list of protected categories of persons eligible for PACE services in 2006, explaining that “we do not believe anyone should be denied enrollment in PACE because of discrimination of any kind.” Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions, 71 Fed. Reg. 71,244, 71,295 (Dec. 8, 2006).

153. Prior to the Revised Rule, 42 C.F.R. § 460.98(b)(3) provided: “The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment.” The Revised Rule amends 42 C.F.R. § 460.98(b)(3) to state: “The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment.” 85 Fed. Reg. at 37,243 (to be codified at 42 C.F.R. § 460.98(b)(3)). The Revised Rule also eliminates protections against sexual orientation

discrimination in 42 C.F.R. § 460.112(a). 85 Fed. Reg. at 37,220, 37,243 (to be codified at 42 C.F.R. § 460.112(a)).

154. Prohibitions of discrimination on the basis of sexual orientation and gender identity were added to regulations regarding group and individual market health insurance plans subject to the ACA and to ACA-created health insurance exchanges and qualified health plans. These prohibitions were added to further the ACA's aim of expanding insurance coverage, which discriminatory marketing practices and benefit designs can thwart. *See* 45 C.F.R. §§ 147.104(e), 155.120(c)(1)(ii), 155.220(j)(2)(i), 156.200(e), & 156.1230(b)(2); *see also* PPACA; Establishment of Exchanges and Qualified Health Plans, 77 Fed. Reg. 18,310, 18,319, 18,415 (March 27, 2012); PPACA; Health Insurance Market Rules, 78 Fed. Reg. 13,406, 13,417 (Feb. 27, 2013); PPACA; Exchange and Insurance Market Standards for 2015 and Beyond, 79 Fed. Reg. 30,240, 30,261 (May 27, 2014); PPACA; HHS Notice of Benefit and Payment Parameters for 2018, 81 Fed. Reg. 94,058, 94,064, 94,152 (Dec. 22, 2016).

155. The Revised Rule eliminates the prohibitions on gender identity and sexual orientation discrimination in these regulations. *See* 85 Fed. Reg. at 37, 219-21, 37,247-48 (to be codified at 45 C.F.R. §§ 147.104(e), 155.120(c)(1)(ii), 155.220(j)(2)(i), 156.200(e), & 156.1230(b)(2)).

156. HHS offers no legal, policy, or cost-benefit analysis for amending these regulations, including the effects they have had during the years they have been in place or the costs and benefits of amending them.

157. HHS's erroneous analysis of discrimination on the basis of sex under longstanding civil rights laws provides no justification for amending these regulations, which were promulgated to advance the goals of other statutory provisions.

158. HHS's amendment of these unrelated regulations to eliminate protections for LGBTQ people is arbitrary and capricious and without legal support.

XII. The Revised Rule's Cost-Benefit Analysis Is Arbitrary and Capricious

159. The Revised Rule fails to address adequately the direct and indirect costs that repeal of protections for LGBTQ people will have on patients, providers, insurers, and the overall health care system.

160. These costs take many forms, none of which the Revised Rule considers. First, out-of-pocket costs for necessary medical procedures will shift from insurers to patients and providers. Under the 2016 Final Rule, most insurers covered these services, but under the Revised Rule, insurers can deny coverage on the basis that these are cosmetic procedures, rather than medically necessary to alleviate gender dysphoria. Thus, many patients may forgo this necessary medical care due to the high cost of these procedures or cover the cost themselves. Providers also would lose out on the revenue from these procedures when patients cannot afford them.

161. Second, insurers' increased transgender exclusions and transgender patients' increased fear of discrimination by health care providers empowered by the Revised Rule will lead to transgender patients delaying or declining to seek care.¹⁵ As such, transgender patients may develop comorbid conditions such as depression, anxiety, drug abuse, and other stress-related conditions. Treating these increased comorbid conditions will increase costs to patients, insurers, providers, and the health system overall.

¹⁵ See Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* at 12 (2010), <https://perma.cc/9SEG-JD2K>; see also S.E. James *et al.*, Nat'l Ctr. for Transgender Equality, *The Report of the 2015 U.S. Transgender Survey* at 98 (2016), <https://perma.cc/9S9L-VJ9C>.

162. Third, patients' delays or failures to obtain treatment will increase the direct cost of treating physical medical conditions and is a patient safety issue that can lead to poor patient outcomes. LGBTQ patients who fear discrimination may delay, or never receive, preventative care such as cancer screenings. Without regular screenings, LGBTQ patients will develop more advanced cancers and other health conditions. Because the cost of treating more advanced diseases far outweighs the cost of preventative care, the Revised Rule will increase costs to patients, insurers, providers, and the overall health care system.

163. The Revised Rule does not consider these costs associated with inviting discrimination against LGBTQ patients, and in particular those who are transgender. Ignoring such substantial costs makes the Revised Rule's cost-benefit analysis seriously flawed and arbitrary and capricious.

164. Indeed, the Revised Rule specifically admits HHS did not take the costs or harms to transgender patients into account, stating: "the Department also lacks the data necessary to estimate the number of individuals who currently benefit from covered entities' policies governing discrimination on the basis of gender identity who would no longer receive those benefits after publication of this rule." 85 Fed. Reg. at 37,225.

165. The costs of prohibiting sex-based discrimination against transgender people in health insurance coverage is minimal compared to the costs associated with inviting such discrimination. The 2016 Final Rule acknowledged this fact, stating that prohibiting discrimination against transgender consumers in health insurance "will have de minimis impact on the overall cost of care and on health insurance premiums." 81 Fed. Reg. at 31,456-57. Moreover, studies have found that providing coverage of transition-related care is extremely cost-effective and reduces costs in the long term. For example, a 2013 survey of employers

found that providing transition-related health care benefits has “zero or very low costs” and utilization rates of approximately 1 per 10,000 to 20,000 employees.¹⁶ Another study found that the cost of providing coverage for treatment of gender dysphoria was about \$0.016 per member per month. It also concluded that this small cost could reduce other costly health risks like depression and drug abuse.¹⁷ Numerous other studies confirm these conclusions.¹⁸

166. The Revised Rule also fails to include in its cost-benefit analysis the costs associated with (1) eliminating gender identity nondiscrimination protections in the CMS regulations promulgated under different statutes, and (2) adopting the broad religious exemptions from Title IX and unrelated statutes. The costs of these changes include those associated with the increased discrimination that will result from the Revised Rule. Failing to consider these costs also makes the Revised Rule arbitrary and capricious.

¹⁶ Jody L. Herman, *Cost and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans*, The Williams Institute of the UCLA School of Law (Sept. 2013), <https://perma.cc/D8J5-FACP>.

¹⁷ William V. Padula *et al.*, *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis*, 31 J. GEN. INTERN. MED. 394, 398 (Oct. 2015), <https://perma.cc/74EW-LZPY>.

¹⁸ See Declaration of Raymond Edwin Mabus, Jr., former Secretary of the Navy, in Support of Plaintiff’s Motion for Preliminary Injunction ¶ 41, *Doe v. Trump*, No. 1:17-cv-1597-CKK (Aug. 31, 2017), ECF No. 13-9, <https://perma.cc/8ZU8-8NGE> (concluding costs associated with providing health care to transgender service members was considered by a former Secretary of the Navy to be “budget dust, hardly even a rounding error”); Padula, *et al.*, *Societal Implications of Health Insurance Coverage for Medically Necessary Services in the U.S. Transgender Population: A Cost-Effectiveness Analysis* at 398, <https://perma.cc/74EW-LZPY> (calculating the costs would be fewer than two pennies per month for every person with health insurance coverage in the United States); Cal. Dep’t of Ins., *Economic Impact Assessment: Gender Nondiscrimination in Health Insurance* (Reg. File No. REG-2011-00023) (Apr. 13, 2012), <https://perma.cc/QJ34-RVNQ> (finding that costs of providing health care did not increase materially when employers adopted policies that prohibited discrimination against transgender individuals).

XIII. The Revised Rule Betrays Discriminatory Animus Against LGBTQ People

167. HHS’s discriminatory animus in promulgating the Revised Rule is evident, as the promulgation of the Revised Rule is just the latest step in its multi-step erasure of LGBTQ people from health care-related nondiscrimination protections.

168. Defendant Severino has a history of anti-LGBTQ sentiments, advocacy, and comments. For example, in 2016, before he became Director of OCR, defendant Severino decried the 2016 Final Rule because it ran counter to some people’s “moral, and religious beliefs about biology” and because, in his opinion, the 2016 Final Rule “create[d] special privileges, new protected classes, or new rights to particular procedures.”¹⁹

169. In 2016, defendant Severino also denounced the Department of Justice’s enforcement of Title IX’s sex discrimination protections as they applied to transgender people as “using government power to coerce everyone, including children, into pledging allegiance to a radical new gender ideology.”²⁰

170. That same year, defendant Severino also stated that he believes transgender military personnel serving openly “dishonors” the service of other service members.²¹ In addition, he referred to a transgender male student involved in a Title IX lawsuit as a “teen biological girl.”²²

¹⁹ Ryan Anderson & Roger Severino, *Proposed Obamacare Gender Identity Mandate Threatens Freedom of Conscience and the Independence of Physicians*, The Heritage Foundation (Jan. 8, 2016), <https://perma.cc/5XKG-S79Z>.

²⁰ Roger Severino, *DOJ’s Lawsuit Against North Carolina Is Abuse of Power*, The Daily Signal (May 9, 2016), <https://perma.cc/3FFM-KFMB>.

²¹ Roger Severino, *Pentagon’s Radical New Transgender Policy Defies Common Sense*, CNSNews (July 1, 2016), <https://perma.cc/VK37-5FP7>.

²² Roger Severino & Jim DeMint, *Court Should Reject Obama’s Radical Social Experiment*, The Heritage Foundation (Dec. 14, 2016), <https://perma.cc/N6K8-HQY5>.

171. In 2018, it was reported that HHS’s OCR was considering defining sex as “a person’s status as male or female based on immutable biological traits identifiable by and before birth,” a definition that is contrary to the legal, medical, and scientific understanding of sex.²³

172. And in 2019, HHS issued a Notification of Nonenforcement of Health and Human Services Grants Regulation, in which it stated that it would no longer enforce regulations that prohibit discrimination based on sex, sexual orientation, or gender identity in grant programs that HHS funds. 84 Fed. Reg. 63,809 (Nov. 19, 2019).

173. With defendant Severino now Director of OCR, defendants seek to eviscerate the nondiscrimination protections Severino denounced.

174. For example, HHS asserts that it considered adding gender identity and sexual orientation discrimination to a definition of “sex” or discrimination “on the basis of sex” under Title IX, but concluded doing so was “inappropriate to do so in light of the ordinary public meaning of discrimination on the basis of sex under Title IX” and because “[a]s a policy matter,” state and local entities “are better equipped to address with sensitivity issues of gender dysphoria, sexual orientation, and any competing privacy interests, especially when young children or intimate settings are involved.” 85 Fed. Reg. at 37,222. Not only has the Supreme Court rejected HHS’s position on the definition of “sex” under Title VII, but the notion that health care protections for LGBTQ people are at odds with “young children” is as offensive as it is telling.

175. As another example, although HHS declares that its position on the meaning of sex discrimination “will not bar covered entities from choosing to grant protections on the basis

²³ Erica L. Green, Katie Benner & Robert Pear, ‘*Transgender*’ Could Be Defined Out of Existence Under Trump Administration, N.Y. Times (Oct. 21, 2018), <https://perma.cc/YQR6-YN2F>.

of sexual orientation and gender identity that do not conflict with any other Federal law,” 85 Fed. Reg. at 37,222, HHS also states that a covered entity’s refusal to make distinctions on the basis of sex “could in some cases violate personal privacy interests and so create a hostile environment under Title IX.” 85 Fed. Reg. at 37,184. This assertion and the cases cited have nothing to do with Section 1557 and what facilities should be available to a patient in a health care setting.

176. HHS also fails to acknowledge that no cognizable legal claim exists based on having to share a restroom or other single-sex facility with a transgender person. HHS’s suggestion to the contrary, *see* 85 Fed. Reg. at 37,190-91, is inconsistent with the rule of law and not a “reasonable” analysis. It serves only to heighten alarm among LGBTQ people and embolden those who attack them with frivolous assertions.

177. The Revised Rule reflects HHS’s animosity toward LGBTQ people.

XIV. The Revised Rule Creates Immediate and Irreparable Harms

178. The Revised Rule cannot change the law and the courts will determine the meaning of Section 1557. However, HHS’s rules have a substantial effect on health care providers and institutions, as well as on the public. The Revised Rule will result in increased discrimination against LGBTQ people, including those with LEP, by health care providers and health insurers. This increased discrimination will directly and irreparably injure plaintiffs, their members, their patients, and the individuals whom they serve.

A. The Revised Rule Will Increase LGBTQ Discrimination by Health Care Providers and Staff and Cause Irreparable Harm to Plaintiffs and the Patients and Individuals They Serve

179. Discrimination delays or denies necessary health care. It also discourages LGBTQ people from seeking care and from fully disclosing personal information that health care providers need for proper diagnosis and treatment.

180. The Revised Rule sends a message to the health care industry and the LGBTQ community that federal law permits discrimination against LGBTQ patients.

181. Indeed, in its Notice of Proposed Rulemaking, HHS acknowledged the 2016 Final Rule “likely induced many covered entities to conform their policies and operations to reflect gender identity as protected classes [sic] under Title IX.” 84 Fed. Reg. at 27,876. And in the Revised Rule, HHS acknowledges that some covered entities may revert to the policies and practices they had in place before the 2016 Final Rule. 85 Fed. Reg. at 37,225. OCR also estimates that 60% of the increase in its anticipated long-term caseload of claims of discrimination are attributable to discrimination claims based on the 2016 Rule’s definition of sex discrimination with respect to gender identity and sex stereotyping, though OCR has not enforced such claims. 85 Fed. Reg. at 37,235.

182. HHS tries to minimize the harm the Revised Rule will create, repeatedly claiming that because a federal district court enjoined enforcement of claims based on the definition of sex discrimination in the 2016 Final Rule in December 2016 and later vacated those provisions, any harm would not be the result of the Revised Rule, which merely is maintaining the status quo. *See, e.g.*, 85 Fed. Reg. at 37,181-82, 37,192, 37,199, & 37,238.

183. HHS’s position is disingenuous at best. HHS has issued a Revised Rule attempting to legislate that claims of discrimination based on LGBTQ status are not “cognizable” under Section 1557. 85 Fed. Reg. at 37,225.

184. Without complete protection from discrimination based on their sex, including discrimination based on their sexual orientation, gender identity, transgender status, or failure to conform to sex stereotypes, LGBTQ people will be discouraged from seeking the health care they need.

185. The Revised Rule also will discourage LGBTQ people from fully disclosing personal information related to their sexuality and gender that health care providers need for proper diagnosis.

186. The Revised Rule will harm plaintiffs, their patients, and the LGBTQ people whom they serve in multiple ways.

1. Harm to Patients and Individuals Whom Plaintiffs Serve

187. LGBTQ individuals and especially transgender and gender-nonconforming people already face particularly acute barriers to care and health disparities that will be compounded by the Revised Rule. A majority of LGBTQ patients fear going to health care providers because of past experiences of anti-LGBTQ bias in health care settings. Many LGBTQ patients report negative experiences, including hostility, discrimination, and denials of care, when they disclose to health care providers their sexual orientation, history of sexual conduct, gender identity, transgender status, or history of gender-affirming medical treatment, and related medical histories.

188. For example, multiple LGBTQ patients at Whitman-Walker have previously been refused medical care, including routine care unrelated to gender dysphoria, by providers outside of Whitman-Walker simply because they are LGBTQ. In one instance, a radiological technician refused to perform an ultrasound for testicular cancer on a transgender patient. In another, a health care worker at a dialysis clinic confronted a Whitman-Walker patient with end-stage renal disease and objected to being involved in the patient's care because of hostility to his sexual orientation. In another, after a Whitman-Walker patient—a transgender teenager—was hospitalized in a local hospital following a suicide attempt, the staff would only address or refer to the young person with pronouns inconsistent with their gender identity, exacerbating the teenager's acutely fragile state of mind. Local hospitals and surgeons have refused to perform

transition-related surgeries on Whitman-Walker transgender patients, even when they routinely perform the very same procedures on non-transgender patients, including in situations when the patient's insurance would have covered the procedure or when the patient was able to pay for the procedure. Many local primary-care physicians unaffiliated with Whitman-Walker have refused to prescribe hormone therapy for transgender patients. And multiple Whitman-Walker patients have been denied prescriptions by pharmacists. Behavioral-health providers at Whitman-Walker report that the vast majority of transgender patients—as many as four out of five—report instances of mistreatment or discrimination by health care providers, hospitals, clinics, doctors' offices, or other facilities outside of Whitman-Walker.

189. Patients of the LA LGBT Center report similar experiences of discrimination by other providers. One transgender patient, who developed profuse bleeding after surgery, was denied treatment at an emergency room and arrived at the LA LGBT Center in distress three days later, having lost a significant amount of blood. Another patient required extensive surgery to repair damage caused by a prior silicone breast-augmentation procedure. But she was turned down by an academic plastic-surgery center in Los Angeles because the surgeon said her health problems were caused by her own poor decision-making and she therefore would not be considered for treatment. By the time she was able to identify a surgeon who was willing to treat her, with the assistance of a physician at the LA LGBT Center, years had passed and her condition had become life-threatening. For patients at the LA LGBT Center, the ability to receive gender-affirming medical care can mean the difference between life and death.

190. In many geographic regions, a majority of LGBTQ people lack a provider whom they consider to be their personal doctor. As a result, when they seek health care services, they will encounter a health care provider with whom they do not have a relationship. This makes

them especially vulnerable to discriminatory treatment from providers who are not LGBTQ-affirming. For some medical specialties, there are only a handful of health care providers in the region who have the expertise necessary to treat a patient for a particular condition, so a denial of care from even one provider could make it practically impossible for an LGBTQ patient to receive any care at all.

191. In a recent study, nearly one in five LGBTQ people, including 31% of transgender people, said that if they were turned away from a hospital, it would be very difficult or impossible to get the health care they need elsewhere.²⁴ The rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider. Even when they are able to get access to care, many LGBTQ individuals report that health care professionals have used harsh language toward them, refused to touch them, used excessive precaution, or blamed the individuals for their health status.²⁵

192. Consequently, LGBTQ patients are disproportionately likely to delay preventative screenings and necessary medical treatment and therefore to end up with more acute health problems and outcomes, raising concerns about patient safety. Research has identified pervasive health disparities for LGBTQ people with respect to cancer, HIV, obesity, mental health, tobacco use, and more. In other words, LGBTQ people, who are disproportionately likely to need a wide range of routine medical care, already have reason to fear, and often do fear, negative consequences of “coming out” to health care providers about their sexual orientation, history of

²⁴ See Mirza & Rooney, *Discrimination Prevents LGBT People From Accessing Health Care*, <https://perma.cc/ZG7E-7WK8>.

²⁵ *Id.*

sexual conduct, gender identity, transgender status, history of gender-affirming medical treatment, and related medical histories.

193. The Revised Rule will exacerbate the acute health disparities LGBTQ people already face. The Revised Rule sends the message that discrimination on the basis of gender identity and sex stereotyping is permissible under federal law, which will increase the number of LGBTQ people who will be denied care.

194. The Revised Rule also encourages LGBTQ people to remain closeted to the extent possible when seeking medical care. But remaining closeted to a health care provider may result in significant adverse health consequences. For instance, a patient who conceals or fails to disclose a same-sex sexual history may not be screened for HIV or other relevant infections or cancers, or may not be prescribed preventative medications such as Pre-Exposure Prophylaxis or PrEP, which is extremely effective at preventing HIV transmission. Patients who fail fully to disclose their gender identity and sex assigned at birth may not undergo medically indicated tests or screenings (such as tests for cervical or breast cancer for some transgender men, or testicular or prostate cancer for some transgender women). The barriers to care are particularly high for transgender people. Nearly one-quarter of transgender people report delaying or avoiding medical care when sick or injured, at least partially because of fear of discrimination by and disrespect from health care providers.²⁶

195. Patients remaining closeted to health care providers also results in increased costs to the health care system. For example, when a patient is closeted, medical providers may not order medically necessary tests or screenings, which has downstream effects such as

²⁶ See Mirza & Rooney, *Discrimination Prevents LGBT People From Accessing Health Care*, <https://perma.cc/ZG7E-7WK8>.

exacerbating a patient's distress and increasing costs to providers and the health care system as a whole for delayed treatment.

196. The Revised Rule will result in increased discrimination against LGBTQ people in the provision of health care and cause harm to the health of LGBTQ people and to public health generally.

2. Harm to Private Health Care Provider Plaintiffs, LGBTQ-Services Plaintiffs, and Health Professional Association Plaintiffs

197. The Revised Rule, which fosters discrimination against LGBTQ people in the provision of health care, frustrates plaintiffs' core missions of providing and advocating for affirming, high-quality care to all LGBTQ people and protecting against discrimination on the basis of LGBTQ status in the delivery of health care and services to patients.

198. In addition, because more LGBTQ patients will delay seeking health care, they will come to Whitman-Walker and the LA LGBT Center, the private health care provider plaintiffs who serve many LGBTQ patients, and members of the health professional association plaintiffs – GLMA and AGLP – with more acute conditions, diseases that are more advanced at diagnosis, less responsive to treatment, or no longer treatable. This delay will strain the resources of providers and increase costs for providers and patients and the health care system in general.

199. The discriminatory experiences LGBTQ patients have with other health care providers erode patients' trust in health care providers overall and thus also challenges the ability of plaintiffs to treat their patients effectively and provide appropriate services and referrals. To provide proper medical care and services to the LGBTQ community, plaintiffs rely on frank and complete communication with their patients and the individuals who seek their services.

Plaintiffs need patients and individuals seeking services to fully disclose all aspects of their

health history, sexual history, and gender identity to provide appropriate care for the patients' health. Without full disclosure, plaintiffs are not able to treat adequately their patients. For instance, plaintiffs need to know patients' sexual history to know whether to test them for HIV or other infections or cancers. And plaintiffs need to be aware of patients' gender identity and sex assigned at birth to order proper screenings and tests – like cervical or breast cancer for some transgender men, or testicular or prostate cancer for some transgender women. The Revised Rule endangers the provider-patient relationship and will harm plaintiffs and their patients by discouraging full disclosure. This also means that medical and health care providers bear increased risk of malpractice when patients do not feel comfortable to fully disclose all aspects of their health history, sexual history, and gender identity.

200. The Revised Rule's effect of increasing discrimination by other providers will lead to increased demand for providers, entities, and individuals who serve the LGBTQ community, like Whitman-Walker, LA LGBT Center, the TransLatin@ Coalition (and its affiliated organizations like FLAS and Arianna's Center), Bradbury-Sullivan Center, and the members of GLMA and AGLP. This increased demand will place a strain on these plaintiffs' resources, leaving them unable to fulfill their organizational missions, spend sufficient time on each patient or individual seeking services, and provide care and services to all individuals. It also will harm LGBTQ people through increased wait times and delays of care that may worsen conditions.

201. In addition, Whitman-Walker, LA LGBT Center, the TransLatin@ Coalition (and some of its affiliated organizations like FLAS and Arianna's Center), and Bradbury-Sullivan Center, as well as the members of GLMA and AGLP and the individual provider plaintiffs, all refer patients to other health care providers. The Revised Rule will harm the ability of these

plaintiffs to refer LGBTQ patients to other providers because they will not know whether these providers will discriminate against their patients and/or refuse to treat their patients under the Revised Rule's personal religious or moral belief exemptions. Thus, these plaintiffs will be required to redirect their staff and resources from providing their own services to assisting patrons in determining who among the health care providers in the region will serve LGBTQ patients in a nondiscriminatory manner.

202. The Revised Rule also will burden the private health care provider and LGBTQ-services plaintiffs by precluding them from carrying out their organizational missions of providing affirming, non-discriminatory care to all LGBTQ patients based on the religious views of a single employee. The sweeping religious exemptions in the Revised Rule encourage individual employees to believe their discriminatory beliefs can prevail over their duties to patients – and to their fellow employees – posing barriers to patient care and creating burdens for the organizations. The private health care provider and LGBTQ-services plaintiffs may be forced to institute costly workarounds and duplicative staff to accommodate the religious views of a single employee, which also may result in unfairly burdening non-objecting employees. These increased costs also may result in a reduction of services and closure of programs, thus frustrating plaintiffs' institutional missions and core functions of providing comprehensive health care and other services to LGBTQ people.

3. Additional Harm to GLMA, AGLP, and Their Members

203. The Revised Rule also will create additional harms to the health professional association plaintiffs GLMA and AGLP, their members, the LGBTQ patients whose interests they represent, and the patients whom their members treat.

204. GLMA works with professional accreditation bodies, such as the Joint Commission, and health-professional associations, on standards, guidelines, and policies that

address LGBTQ health and protect individual patient health and public health in general. The Revised Rule prevents GLMA from achieving its goals with professional accreditation bodies by preventing such bodies from holding health care providers accountable for discrimination against LGBTQ people.

205. For a health care organization to participate in and receive federal payment from Medicare or Medicaid programs, the organization must obtain a certification of compliance with health and safety requirements. That certification is achieved based on a survey conducted either by a state agency on behalf of the federal government, or by a federally recognized national accrediting organization, like the Joint Commission. Accreditation surveys include requirements that health care organizations not discriminate on the basis of sex, sexual orientation, or gender identity in providing services or in employment. The Revised Rule presents a direct conflict with nondiscrimination standards the Joint Commission has adopted and all the major health-professional associations stating that health care providers should not discriminate in providing care for patients and clients because of sexual orientation or gender identity.

206. The Revised Rule invites health care organizations who discriminate against LGBTQ people to become accredited. The Revised Rule conflicts with GLMA's mission of achieving and enforcing accreditation standards relating to nondiscrimination.

207. Members of GLMA and AGLP also will be harmed by the Revised Rule because some members are employed by health care organizations that may rely on the religious and moral exemptions in the Revised Rule to deny care or discriminate against LGBTQ patients. The Revised Rule encourages religiously-affiliated health care employers to discriminate against employees who are GLMA or AGLP members for adhering to and enforcing their medical and

ethical obligations to treat all patients in a nondiscriminatory manner, including providing all medically-necessary care that is in LGBTQ patients' best interests.

208. In addition, the Revised Rule invites harassment and discriminatory treatment of GLMA and AGLP members in the workforce by fellow employees. The Revised Rule sends a message that discrimination against LGBTQ health care providers and their LGBTQ patients is permissible. GLMA and AGLP members and their LGBTQ patients are stigmatized and demeaned by this message that LGBTQ people are not deserving of legal protections in the health care context. The Revised Rule thus frustrates GLMA's and AGLP's missions of achieving and enforcing safe workspaces for LGBTQ health professionals and non-discriminatory health care services for their LGBTQ patients.

4. Additional Harm to the TransLatin@ Coalition, Its Members, and the Individuals it Serves

209. The Revised Rule also will harm the TransLatin@ Coalition, its members, its affiliated organizations, and the individuals whom the Coalition serves in that the harms the Revised Rule will exact on LGBTQ people, particularly those who are transgender, will be exacerbated for those with LEP. The Revised Rule's elimination of notice and tagline requirements will make it more difficult for LGBTQ people with LEP to be aware of their rights, which language services and aids are available, how to access such services, and how to handle discrimination and complaints. The health care system was already difficult to navigate for LEP individuals, and the Revised Rule serves to exacerbate those difficulties and undermines access to health care, health insurance, and legal redress. The Revised Rule will harm the TransLatin@ Coalition's mission and members by making it more difficult to access health care and by decreasing protections from discrimination.

210. The Revised Rule’s elimination of the unitary standard also harms the TransLatin@ Coalition, its members, and individuals whom it serves by making it more difficult to bring claims of intersectional discrimination. Rather than being able to assert claims under a unitary standard, intersectional discrimination claims will be subject to different standards, enforcement mechanisms, and remedies based on which identities are at issue.

B. The Revised Rule Will Result in Increased Discrimination by Health Plans, Particularly Against Persons Seeking Gender-Affirming Care

211. Many private and public plans resist coverage of medically necessary procedures, whether through blanket exclusions of “sex change” or “sex transition” procedures, or through denials of coverage of specific procedures. Many plans that do not contain blanket exclusions still exclude many essential types of surgeries related to gender transition, such as facial or chest surgery.

212. Many insurers also deny coverage of other specific treatments needed to complete an individual’s transition on the grounds that the procedure is “cosmetic” – either by relying on general plan language excluding cosmetic procedures or concluding that a procedure is not medically necessary. Examples of procedures that are categorically excluded as “cosmetic” in many plans and by many utilization reviewers include:

- a. Surgeries of the head and face, such as hair transplant, scalp advancement, brow reduction, lip reduction or augmentation, rhinoplasty, cheek and chin contouring, jawline modification, blepheroptasty, and other facial feminization techniques for transgender women;
- b. Laser hair removal and electrolysis, on the face and elsewhere on the body;

- c. Surgeries involving the neck, such as cartilage reduction (modification of the Adam's Apple) and vocal feminization surgery;
- d. Breast augmentation and reduction;
- e. Other body contouring procedures, such as waist reduction, hip/buttocks implants, fat transfer, pectoral implants; and
- f. Lessons/training to modify the vocal range.

213. Relying on its definition of “on the basis of sex” to include gender identity and to forbid discrimination against transgender individuals, the 2016 Final Rule helped persuade Medicaid administrators, insurance company personnel, and employee health plan sponsors to eliminate outdated exclusions and to agree to cover procedures when supported by evidence of medical necessity. Following its promulgation, the 2016 Final Rule led to a decrease in discriminatory policies and practices.²⁷ A recent study of 37 states in the federal marketplace showed that 97% of plans analyzed did not contain blanket exclusions of transition-related care in 2019.²⁸

214. By eliminating the 2016 Final Rule’s definition of “on the basis of sex” and the explicit prohibitions on “categorical coverage exclusion[s] or limitation[s] for all health services related to gender transition” and denials, limitations, or restrictions “for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual,” 81 Fed. Reg. at 31,472 (formerly codified at 45 C.F.R. § 92.207(b)(4)-(5)), the Revised Rule invites reversal of much of this progress, leading to a

²⁷ Gruberg & Bewkes, *The ACA’s LGBTQ Nondiscrimination Regulations Prove Crucial*, <https://perma.cc/CTP2-UMEJ>.

²⁸ Out2Enroll, *Summary of Findings: 2020 Marketplace Plan Compliance with Section 1557*, <https://perma.cc/WU25-C9BN>. This is consistent with summaries from 2017, 2018, and 2019.

reduction in coverage and access to medically necessary health care for transgender and gender nonconforming patients.

215. In addition, the Revised Rule's narrow interpretation of what constitutes a covered entity similarly will result in a reduction in coverage and access to medically necessary health care for transgender and gender nonconforming patients.

216. Increased discrimination by health insurance plans will harm plaintiffs and the patients and individuals whom they serve. Plaintiffs that provide health care services will face increased costs because many private and public plans will refuse to cover medically necessary procedures based on the Revised Rule's elimination of protections against gender identity discrimination. Plaintiffs, in turn, will be forced to either cover the costs of these medically necessary procedures, or turn away LGBTQ patients who need these services but cannot afford to pay for them out of pocket. Likewise, patients may forgo necessary medical care due to the high cost of these procedures or cover the cost themselves.

C. The Revised Rule Will Result in Increased Discrimination towards Patients with Limited English Proficiency

217. Language access protections are required to prevent discrimination based on national origin. These services are important because ineffective communication between health care providers and LEP patients for the purposes of diagnosis, treatment options, proper use of medication, obtaining informed consent, and insurance coverage can result in adverse health consequences or death.

218. The Revised Rule eliminates the requirement that covered entities take reasonable steps to provide meaningful access to "*each individual* with LEP eligible to be served or likely to be encountered" and replaces it with a general reference to "LEP individuals." *See, e.g.*, 85 Fed.

Reg. at 37,245. However, focusing on LEP individuals in general as opposed to each individual will result in some individuals not receiving the services they need for meaningful access.

219. In addition, the Revised Rule eliminates the existing requirement that non-discrimination notices include the availability of language assistance services and taglines in the top 15 languages spoken by LEP individuals in a state. HHS “acknowledges the potential of reduced awareness of the availability of language services by LEP individuals by the changes made in this rule, or downstream effects on malpractice claims due to less awareness,” 85 Fed. Reg. at 37,235, yet HHS dismissed these negative effects claiming enforcement of Section 1557 will diminish them.

220. The Revised Rule will harm LEP patients, including members of the TransLatin@ Coalition and those the Coalition and its affiliated organizations (like FLAS and Arianna’s Center) serve, as well as the LEP patients private health care provider plaintiffs serve, by diminishing or eliminating meaningful access to health care because they will not be aware of their rights or the programs or services available to them.

221. The weakening of protections for LEP individuals will result not only in poorer health outcomes for LEP individuals, but also in increased costs and burdens for plaintiffs. As a result of the Revised Rule, private health care and individual provider plaintiffs will face increased burdens due to fewer clients being aware of their language access rights and the likelihood that more people will turn to them for help in their language, rather than other covered health care providers.

222. For example, the weakening of protections for LEP individuals will harm LEP patients of private health care providers who get care elsewhere and who private health care providers need to refer outside their organizations for specialty care, as they will no longer

benefit from the notices, taglines, and additional language access provisions that are critical to ensure meaningful access to care.

223. The weakening of protections also will burden private health care and individual provider plaintiffs, as well as members of health professional association plaintiffs, because patients will come to them sicker due to inadequate care elsewhere, and more people may come to them because their LEP services will remain robust.

224. In addition, the weakening of protections for LEP individuals will harm private health care providers and individual provider plaintiffs, as well as members of health professional association plaintiffs, as it will place them at an increased risk for malpractice claims linked to inadequate language access.

FIRST CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(A)
Arbitrary and Capricious

225. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

226. Defendants are subject to the Administrative Procedure Act (“APA”), 5 U.S.C. § 551 *et seq.*

227. The APA provides that courts must “hold unlawful and set aside agency action” that is “arbitrary, capricious, [or] an abuse of discretion.” 5 U.S.C. § 706(2)(A).

228. The Revised Rule is arbitrary and capricious because defendants’ justifications for repealing critical anti-discrimination protections run counter to the evidence before the agency and disregard material facts and evidence, defendants fail to supply a reasoned explanation for their policy change from the 2016 Final Rule to the Revised Rule, defendants have failed to consider important aspects of the problem, including the Revised Rule’s interference with

current law, and defendants failed to account properly for the costs and benefits of the Revised Rule.

229. The Revised Rule relies primarily on a single ruling and the federal government's litigation position in the *Bostock* case and related litigation to justify HHS's rejection of long-standing authority that has defined discrimination on the basis of sex in a variety of federal civil rights laws to include discrimination against individuals who are LGBTQ. The Supreme Court now has rejected HHS's position.

230. The Revised Rule also eliminates, contrary to statutory authority, the unitary legal standard for enforcement of violations of Section 1557, replacing it with a fractured approach that will complicate and make it more difficult to bring discrimination claims under Section 1557, particularly claims of intersectional discrimination.

231. The Revised Rule's elimination of the explicit recognition of private rights of action and the availability of compensatory damages under Section 1557 also will confuse the public and mislead many individuals into not asserting their legal rights.

232. In addition, contrary to the statutory language of Section 1557, the Revised Rule imports broad and sweeping exemptions for discrimination based on personal religious or moral belief from both the named statutes in Section 1557 and other statutes, like the Religious Freedom Restoration Act (42 U.S.C. § 2000bb *et seq.*), which Section 1557 does not reference. These exemptions invite individual health care providers, health care entities (hospitals, clinics etc.), and insurers across the country to opt out of treating patients, including many transgender patients, if they believe doing so would compromise their faith. Defendants' attempt to create new religious exemptions in Section 1557 is contrary to law and endangers patients' health in the name of advancing the religious beliefs of those who are entrusted with caring for them – a result

sharply at odds with HHS’s stated mission, which is to “enhance and protect the health and well-being of all Americans” and to “provid[e] for effective health and human services.” It also adversely affects health care providers that serve and treat the LGBTQ community because (1) individual health care employees may decline to serve patients based on religious objections, and (2) their ability to refer patients to other providers will be impaired, as the Revised Rule invites those other providers to discriminate against their LGBTQ patients.

233. The Revised Rule also arbitrarily limits the scope of Section 1557, cutting back on the entities subject to the statute, contrary to the plain language of Section 1557.

234. Defendants also have failed to provide a sufficient explanation for the decision to eliminate the references to sexual orientation and gender identity discrimination in unrelated regulations promulgated under different statutes. Neither the evidence before the agency nor the weight of the legal authority supports the elimination of these protections.

235. Defendants also have failed to provide a sufficient explanation for the decision to eliminate protections against discrimination on the basis of association. Neither the evidence before the agency nor the weight of the legal authority supports the elimination of these protections.

236. The Revised Rule also is arbitrary and capricious in that it eliminates the requirement of notice of nondiscrimination requirements and access to language protections without adequate justification, undermining the ACA’s charge to ensure individuals have access to health care and health insurance.

237. The Revised Rule fails to consider important regulatory costs, including significant direct or indirect health costs to plaintiffs, their patients, and public health and safety.

238. The Revised Rule therefore is arbitrary, capricious, [or] an abuse of discretion” in violation of the APA. 5 U.S.C. § 706(2)(A).

239. Defendants’ violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

SECOND CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(A)
Not in Accordance with Law

240. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

241. Under the APA, a court must “hold unlawful and set aside agency action” that is “not in accordance with law.” 5 U.S.C. § 706(2)(A).

242. The Revised Rule is not in accordance with law because it conflicts with the Supreme Court’s ruling in *Bostock* that discrimination on the basis of a person’s sexual orientation or transgender status is discrimination on the basis of sex under Title VII, and rejects the well-established understanding of “sex” under longstanding civil rights laws as including such discrimination.

243. The Revised Rule’s elimination of protections based on sexual orientation and gender identity in unrelated regulations promulgated under different statutes likewise conflicts with controlling legal authority regarding the meaning of “sex.”

244. The Revised Rule’s elimination of protections against discrimination on the basis of association contravenes existing case law and the underlying statutes and therefore is , not in accordance with law.

245. The Revised Rule conflicts with the statutory language and purpose of Section 1557 by failing to make the enforcement mechanisms provided by Title VI, Title IX, the Age

Discrimination Act, and the Rehabilitation Act available in the case of discrimination against a person based on any characteristic protected by these statutes.

246. The Revised Rule also conflicts with the statutory language of Section 1557 by importing broad and sweeping exemptions based on personal religious or moral belief from the identified statutes in Section 1557 and other statutes, including the Religious Freedom Restoration Act (42 U.S.C. § 2000bb *et seq.*), which Section 1557 does not reference.

247. In addition, the Revised Rule conflicts with the statutory language of Section 1557 by limiting the entities covered under Section 1557.

248. The Revised Rule violates Section 1554 of the ACA, which explicitly prohibits the Secretary of HHS from promulgating any regulation that “creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care” or “impedes timely access to health care services.” 42 U.S.C. § 18114. The Revised Rule creates unreasonable barriers and impedes timely access to health care by reversing protections against discrimination of historically marginalized communities and eliminating access to language provisions.

249. The Revised Rule therefore is “not in accordance with law” as required by the APA. 5 U.S.C. § 706(2)(A).

250. Defendants’ violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

THIRD CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(C)
Exceeds Statutory Authority

251. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

252. Under the APA, a court must “hold unlawful and set aside agency action” that is “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(C).

253. Federal agencies do not have the power to act unless Congress confers the power upon them. Defendants were not given the power to alter Section 1557’s statutory terms, but that is precisely what the Revised Rule attempts to do. The Revised Rule unduly limits the explicit nondiscrimination protections against sex discrimination set forth in Section 1557 by purporting to preclude claims of discrimination based on an individual’s LGBTQ status. It also places health care services for LGBTQ people, gender nonconforming people, and other consumers at risk without congressional authorization to make these changes.

254. The Revised Rule’s elimination of a unitary legal standard to address violations of Section 1557 and limitation on the entities covered under Section 1557 likewise is contrary to the language and intent of Section 1557 and exceeds HHS’s authority.

255. The Revised Rule also amends a series of unrelated regulations to conform with the Revised Rule. The Revised Rule erases not only existing protections for LGBTQ people in the 2016 Final Rule, but eliminates such protections in other regulations, which were promulgated pursuant to the authority granted by several different statutes, including Section 1321(a) and the provisions of the ACA, Social Security Act, and other statutory authority, not Section 1557.

256. The Revised Rule also eliminates notice requirements and access to language protections, undermining the ACA’s central purpose to ensure individuals have access to health care and health insurance.

257. The Revised Rule therefore is “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right” in violation of the APA. 5 U.S.C. § 706(2)(C).

258. Defendants’ violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

FOURTH CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(B)
and U.S. Constitution, Fifth Amendment, Equal Protection Component

259. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

260. Under the APA, a court must “hold unlawful and set aside agency action” that is “contrary to constitutional right, power, privilege, or immunity.” 5 U.S.C. § 706(2)(B).

261. The Fifth Amendment’s Due Process Clause provides that no person shall be deprived of life, liberty, or property without due process of law.

262. The Due Process Clause includes within it a prohibition against the denial of equal protection of the laws by the federal government, its agencies, or its officials or employees.

263. The purpose and effect of the Revised Rule are to discriminate against plaintiffs, their patients, the individuals they serve, and their members based on their sex, gender identity, transgender status, gender nonconformity, and exercise of their fundamental rights, including the rights to bodily integrity and autonomous medical decision-making, and the rights to live and express oneself consistent with one’s gender identity.

264. The Revised Rule also is intended to have and will have a disproportionate impact on LGBTQ people. The Revised Rule places an impermissible special burden on these individuals.

265. LGBTQ people have suffered a long history of discrimination and continue to suffer that discrimination. They are part of discrete and insular groups and lack the power to protect their rights through the political process.

266. Transgender people have a gender identity that differs from the sex assigned to them at birth. A person's gender identity is a core, defining trait fundamental to a person's sense of self and personhood.

267. Requiring a person to abandon their gender identity as a condition to equal treatment violates the Equal Protection Clause.

268. Discrimination on the basis of sex, including on the basis of gender identity, transgender status, sexual orientation, and failure to conform to sex stereotypes, is presumptively unconstitutional and subject to heightened scrutiny.

269. Similarly, discrimination based on the exercise of a fundamental right is presumptively unconstitutional and is subject to strict scrutiny.

270. The Revised Rule lacks a rational or legitimate justification, let alone the important or compelling one that is constitutionally required. The Revised Rule also lacks adequate tailoring under any standard of review.

271. Defendants' encouragement of discrimination against LGBTQ people deprives LGBTQ people of their right to equal dignity and stigmatizes them as second-class citizens.

272. The Revised Rule therefore violates the Equal Protection Clause of the Fifth Amendment of the U.S. Constitution and must be set aside under the APA and the Fifth Amendment.

273. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

FIFTH CLAIM FOR RELIEF

**Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(B)
and U.S. Constitution, Fifth Amendment, Substantive Due Process**

274. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

275. Under the APA, a court must “hold unlawful and set aside agency action” that is “contrary to constitutional right, power, privilege, or immunity.” 5 U.S.C. § 706(2)(B).

276. The Fifth Amendment’s Due Process Clause protects individuals’ substantive rights to be free to make certain decisions central to privacy, bodily autonomy, integrity, self-definition, intimacy, and personhood without unjustified governmental intrusion. Those decisions include the right to transition-related medical treatment, as well as the right to live openly and express oneself consistent with one’s gender identity.

277. By encouraging health care providers and insurers to interfere with and unduly burden patients’ access to medically necessary health care, the Revised Rule violates the rights of plaintiffs to privacy, liberty, dignity, and autonomy as guaranteed by the Fifth Amendment.

278. A person’s gender identity and ability to live and express oneself consistent with one’s gender identity without unwarranted governmental interference is a core aspect of each person’s autonomy, dignity, self-definition, and personhood. By encouraging health care providers and insurers to deny or otherwise interfere with individuals’ access to gender-affirming medical care, including surgical procedures, hormone therapy, and other medically necessary care, and by interfering with the ability of transgender and gender-nonconforming individuals to live and express themselves in accordance with their gender identities, the Revised Rule infringes on patients’ interests in privacy, liberty, dignity, and autonomy protected by the Fifth Amendment.

279. There is no legitimate interest supporting the Revised Rule’s infringement on patients’ fundamental rights, let alone an interest that can survive the elevated scrutiny required to justify infringement of these fundamental rights.

280. The Revised Rule therefore violates the Due Process Clause of the Fifth Amendment of the U.S. Constitution and must be set aside under the APA and the Fifth Amendment.

281. Defendants’ violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

SIXTH CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(B)
and U.S. Constitution, First Amendment, Free Speech

282. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

283. Under the APA, a court must “hold unlawful and set aside agency action” that is “contrary to constitutional right, power, privilege, or immunity.” 5 U.S.C. § 706(2)(B).

284. The Free Speech Clause of the First Amendment to the United States Constitution declares: “Congress shall make no law . . . abridging the freedom of speech.” U.S. Const. amend. I. The Free Speech Clause prohibits the government from “chilling” a person’s right to free expression.

285. A person’s disclosure of their transgender or gender nonconforming status, speech or expression that discloses gender identity, and a person’s gendered speech and expressive conduct all receive constitutional protection under the First Amendment.

286. The Revised Rule has the purpose and effect of chilling constitutionally protected First Amendment activity. As a result of the Revised Rule, an increased number of LGBTQ

people will remain closeted in health care settings and to doctors, nurses, and other healthcare providers and will decline to disclose their sexual orientation, transgender status, or gender identity.

287. Further, an increased number of LGBTQ people will decline to engage in gendered speech and expression, including by declining to disclose related medical histories—even when that self-censorship impedes the ability of their health care providers to provide appropriate treatment and results in negative health consequences to the patients and to public health.

288. The Revised Rule will chill a patient of ordinary firmness from making such disclosures.

289. The Revised Rule violates the Free Speech Clause of the First Amendment because it impermissibly burdens the exercise of patients’ constitutionally protected speech, expression and expressive conduct based on the content and viewpoint of patients’ speech.

290. In addition, the Revised Rule is overbroad because it will chill protected First Amendment activity.

SEVENTH CLAIM FOR RELIEF
Violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(B)
and U.S. Constitution, First Amendment, Establishment Clause

291. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

292. Under the APA, a court must “hold unlawful and set aside agency action” that is “contrary to constitutional right, power, privilege, or immunity.” 5 U.S.C. § 706(2)(B).

293. The Establishment Clause of the First Amendment to the United States Constitution declares: “Congress shall make no law respecting an establishment of religion.”

U.S. Const. amend. I. The Establishment Clause prohibits the government from favoring one religion over another, or religion over nonreligion.

294. The Establishment Clause permits the government to provide religious accommodations or exemptions from generally applicable laws only if, among other requirements, the accommodation (1) lifts a substantial, government-imposed burden on the exercise of religion, and (2) does not shift substantial costs or burdens onto a discrete class of third parties, without regard for the third parties' interests. In other words, the government may "accommodate" religion in accordance with the Free Exercise Clause, but it may not "promote" religion.

295. The Revised Rule violates the Establishment Clause by creating expansive religious exemptions for health care providers, plans, and employees at the expense of third parties – namely, plaintiffs, other providers, and most importantly the patients and the individuals whom plaintiffs serve. It invites health care providers, including insurance companies, hospitals, doctors, and nurses, to deny LGBTQ patients necessary medical treatment based on their religious beliefs.

296. The effect of the Revised Rule will be that patients who seek care at odds with the religious beliefs of a health care provider or employee of a health care provider may be delayed in receiving care (including emergency care) or denied care altogether.

297. The Revised Rule also will burden plaintiffs by precluding them from carrying out their organizational missions based solely on the religious views of a single employee.

298. In addition, plaintiffs will be harmed because their ability to refer LGBTQ patients to other providers will be affected in that they will not know whether these providers will discriminate against their patients and/or refuse to treat their patients under the Revised

Rule's personal religious or moral belief exemptions. Plaintiffs thus will be required to redirect their staff and resources from providing their own services to assisting patrons in determining who among the health care providers in the region will serve LGBTQ patients in a nondiscriminatory manner.

299. The Revised Rule violates the Establishment Clause because it:

- (a) has the primary purpose and effect of favoring, preferring, and endorsing certain religious beliefs and certain religious denominations over others and over nonreligion;
- (b) has the primary purpose and effect of preferring the religious beliefs of some people and institutions over the lives, health, and other rights and interests of third parties;
- (c) impermissibly entangles government with religion;
- (d) makes plaintiffs, their patients, and other third parties bear the costs and harms of objecting employees' religious beliefs or religious exercise; and
- (e) imposes on plaintiffs a requirement to accommodate employees' religious objections without taking constitutionally required account of the actual burdens (if any) on the objectors or the effects on or harms to plaintiffs, their patients, or the greater public health.

300. Those who are denied coverage will suffer the stigma of government-sanctioned discrimination. They also will be forced to either endure significant psychological burdens or, if they can afford it, pay for treatment out-of-pocket. The Revised Rule favors religion at the expense of LGBTQ patients without regard for LGBTQ patients' interests. The Revised Rule contains no provision for balancing or accounting for a patient's right to care. Instead, it applies

categorically to deny patients the right to medical treatment based on a provider's religious or moral beliefs.

301. The Revised Rule therefore violates the Establishment Clause of the First Amendment of the U.S. Constitution and must be set aside under the APA and the Establishment Clause.

302. Defendants' violations cause ongoing harm to plaintiffs, their patients, the individuals they serve, and their members.

EIGHTH CLAIM FOR RELIEF
Equitable Relief to Preserve Remedy

303. Plaintiffs repeat and incorporate by reference each allegation of the prior paragraphs as if fully set forth herein.

304. The Revised Rule will become effective on August 18, 2020 unless it is enjoined. Plaintiffs are entitled to a full, fair, and meaningful process to adjudicate the lawfulness of the Revised Rule before being required to implement its far-reaching and harmful requirements.

305. Plaintiffs will suffer irreparable injury by implementation of the Revised Rule, which would erode hard-won trust between LGBTQ people and their health care providers, stigmatize and traumatize patients, interfere with medical procedures and operations, and result in delays and denials of care leading to physical harm and even death. Preliminary and permanent injunctive relief is needed to ensure that plaintiffs' injuries are fully remedied.

306. Injunctive relief also is needed to prevent the immediate harm resulting from the Revised Rule. Patients need assurance that they will receive complete, accurate information and timely and responsive medical care in an environment that protects their constitutional rights and does not expose them to stigma and harm. This Court should step in to protect plaintiffs' institutions, their patients, the individuals they serve, and their members, in addition to the

foremost principle guiding medical providers in responding to those in need of assistance and care – first, do no harm.

307. Accordingly, to ensure that plaintiffs receive meaningful relief should they prevail in this action, the Court should preliminarily and permanently enjoin defendants from implementing the Revised Rule.

REQUEST FOR RELIEF

Wherefore, plaintiffs pray that the Court grant the following relief:

- A. Declare that the Revised Rule is unlawful and unconstitutional through a declaratory judgment under 28 U.S.C. § 2201(a) and 5 U.S.C. § 706(a);
- B. Set aside and vacate the Revised Rule;
- C. Preliminarily and permanently enjoin the implementation and enforcement of the Revised Rule;
- D. Award reasonable attorneys' fees, costs, and expenses; and
- E. Award any other further and additional relief the Court deems just and proper.

Dated: June 22, 2020

Respectfully submitted,

LAMBDA LEGAL DEFENSE
AND EDUCATION FUND, INC.

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* *Motion for admission pro hac vice pending.*

** *Application for admission to U.S. District
Court for the District of Columbia forthcoming.*

Counsel for Plaintiffs

EXHIBIT 1



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Part IV

Department of Health and Human Services

Office of the Secretary

45 CFR Part 92

Nondiscrimination in Health Programs and Activities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 92

RIN 0945-AA02

Nondiscrimination in Health Programs and Activities

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: This final rule implements Section 1557 of the Affordable Care Act (ACA) (Section 1557). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. The final rule clarifies and codifies existing nondiscrimination requirements and sets forth new standards to implement Section 1557, particularly with respect to the prohibition of discrimination on the basis of sex in health programs other than those provided by educational institutions and the prohibition of various forms of discrimination in health programs administered by the Department of Health and Human Services (HHS or the Department) and entities established under Title I of the ACA. In addition, the Secretary is authorized to prescribe the Department's governance, conduct, and performance of its business, including, here, how HHS will apply the standards of Section 1557 to HHS-administered health programs and activities.

DATES: *Effective Date:* This rule is effective July 18, 2016.

Applicability Dates: The provisions of this rule are generally applicable on the date the rule is effective, except to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Eileen Hanrahan at (800) 368-1019 or (800) 537-7697 (TDD).

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register**

online database through *Federal Digital System (FDsys)*, a service of the U.S. Government Printing Office. This database can be accessed via the Internet at <http://www.gpo.gov/fdsys>.

I. Background

Section 1557 of the ACA provides that an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. 1681 *et seq.* (sex), the Age Discrimination Act of 1975 (Age Act), 42 U.S.C. 6101 *et seq.* (age), or Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794 (disability), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the Act or its amendments. Section 1557 states that the enforcement mechanisms provided for and available under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of addressing violations of Section 1557.

Section 1557(c) of the ACA authorizes the Secretary of the Department to promulgate regulations to implement the nondiscrimination requirements of Section 1557. In addition, the Secretary is authorized to prescribe regulations for the Department's governance, conduct, and performance of its business, including how HHS applies the standards of Section 1557 to HHS-administered health programs and activities.¹

A. Regulatory History

On August 1, 2013, the Office for Civil Rights of the Department (OCR) published a Request for Information (RFI) in the **Federal Register** to solicit information on issues arising under Section 1557. OCR received 402 comments; one-quarter (99) were from organizational commenters, with the remainder from individuals.

On September 8, 2015, OCR issued a proposed rule, "Nondiscrimination in Health Programs and Activities," in the **Federal Register**, and invited comment on the proposed rule by all interested parties.² The comment period ended on November 9, 2015. In total, we received approximately 24,875 comments on the proposed rule. Comments came from a wide variety of stakeholders, including,

but not limited to: Civil rights/advocacy groups, including language access organizations, disability rights organizations, women's organizations, and organizations serving lesbian, gay, bisexual, or transgender (LGBT) individuals; health care providers; consumer groups; religious organizations; academic and research institutions; reproductive health organizations; health plan organizations; health insurance issuers; State and local agencies; and tribal organizations. Of the total comments, 23,344 comments were from individuals. The great majority of those comments were letters from individuals that were part of mass mail campaigns organized by civil rights/advocacy groups.

B. Overview of the Final Rule

This final rule adopts the same structure and framework as the proposed rule: Subpart A sets forth the rule's general provisions; Subpart B contains the rule's nondiscrimination provisions; Subpart C describes specific applications of the prohibition on discrimination to health programs and activities; and Subpart D describes the procedures that apply to enforcement of the rule.

OCR has made some changes to the proposed rule's provisions, based on the comments we received. Among the significant changes are the following.

Section 92.4 now provides a definition of the term "national origin."

OCR decided against including a blanket religious exemption in the final rule; however, the final rule includes a provision noting that insofar as application of any requirement under the rule would violate applicable Federal statutory protections for religious freedom and conscience, such application would not be required.

OCR has modified the notice requirement in § 92.8 to exclude publications and significant communications that are small in size from the requirement to post all of the content specified in § 92.8; instead, covered entities will be required to post only a shorter nondiscrimination statement in such communications and publications, along with a limited number of taglines. OCR also is translating a sample nondiscrimination statement that covered entities may use in fulfilling this obligation. It will be available by the effective date of this rule.

In addition, with respect to the obligation in § 92.8 to post taglines in at least the top 15 languages spoken nationally by persons with limited English proficiency, OCR has replaced the national threshold with a threshold

¹ 5 U.S.C. 301.

² 80 FR 54172 (Sept. 8, 2015).

requiring taglines in at least the top 15 languages spoken by limited English proficient populations statewide.

OCR has changed § 92.101 to provide that sex-specific health programs or activities are allowable only where the covered entity can demonstrate an exceedingly persuasive justification, *i.e.*, that the sex-specific program is substantially related to the achievement of an important health-related or scientific objective.

OCR has changed § 92.201, addressing the obligation to take reasonable steps to provide meaningful access. That section now requires the Director to evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue to the individual with limited English proficiency, and to take into account all other relevant factors, including whether the entity has developed and implemented an effective language access plan, appropriate to its particular circumstances. The final rule deletes the specific list of illustrative factors set out in the proposed rule.

Also, OCR has changed § 92.203, addressing accessibility of buildings and facilities for individuals with disabilities, to require covered entities that were covered by the 2010 Americans with Disabilities Act (ADA) Standards for Accessible Design prior to the effective date of this final rule to comply with those standards for new construction or alterations by the effective date of the final rule. The final rule also narrows § 92.203's safe harbor for building and facility accessibility so that compliance with the Uniform Federal Accessibility Standards (UFAS) will be deemed compliance with this part only if construction or alteration was commenced before the effective date of the final rule and the facility or part of the facility was not covered by standards under the ADA. As nearly all covered entities under the final rule are already covered by the ADA standards, these changes impose a *de minimis* cost.

Section 92.301 has been changed to clarify that compensatory damages for violations of Section 1557 are available in administrative and judicial actions to the extent they are available under the authorities referenced in Section 1557. Finally, we have added a severability clause to § 92.2, to indicate our intention that the rule be construed to give the maximum effect permitted by law to each provision.

In responding to the comments it received on the proposed rule, OCR has provided a thorough explanation of each of these changes in the preamble. OCR has also clarified some of the

nondiscrimination requirements of Section 1557 and made some technical changes to the rule's provisions. In addition, we have added some definitions to proposed § 92.4, as summarized in the preamble to this final rule.

II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments

A. General Comments

OCR received a large number of comments asking that we categorically declare in the final rule that certain actions are or are not discriminatory. For example, some commenters asked that OCR state that a modification to add medically necessary care, or a prohibition on exclusions of medically necessary services, is never a fundamental alteration to a health plan. Similarly, other commenters asked that OCR include a statement in the final rule that an issuer's refusal to cover core services commonly needed by individuals with intellectual disabilities is discrimination on the basis of disability. Still other commenters asked that OCR state that limiting health care and gender transition services to transgender individuals over the age of 18 is discriminatory. Other commenters asked that OCR state that it is discriminatory to require individuals with psychiatric disabilities to see a mental health professional in order to continue receiving treatment for other conditions.

Many of these same commenters asked that OCR supplement the final rule with in-depth explanations and analyses of examples of discrimination. For example, several commenters asked that OCR add an example of discrimination in research trials. Similarly, many other commenters asked that OCR add an example of what they considered to be disability discrimination in health insurance practices, such as higher reimbursement rates for care in segregated settings.

OCR appreciates the commenters' desire for further information on the application of the rule to specific circumstances. OCR's intent in promulgating this rule is to provide consumers and covered entities with a set of standards that will help them understand and comply with the requirements of Section 1557. Covered entities should bear in mind the purposes of the ACA and Section 1557—to expand access to care and coverage and eliminate barriers to access—in interpreting requirements of the final rule. But we neither address every scenario that might arise in the

application of these standards nor state that certain practices as a matter of law are “always” or “never” permissible. The determination of whether a certain practice is discriminatory typically requires a nuanced analysis that is fact-dependent. Nonetheless, OCR has included in the preamble a number of examples of issues and circumstances that may raise compliance concerns under the final rule.

OCR also received several comments, primarily from representatives of the insurance industry, recommending that where specific Centers for Medicare & Medicaid Services (CMS) or State requirements apply to covered entities, OCR should either (1) harmonize all standards with existing CMS rules, or (2) allow issuers to be deemed compliant with Section 1557 if they are compliant with existing Federal or State law. For example, some commenters requested that compliance with CMS regulations that pertain to qualified health plans or insurance benefit design, such as prescription drug formularies designed by a pharmacy and therapeutics committee, be deemed compliance with the final rule on Section 1557. These commenters were concerned that CMS or a State might approve a plan that OCR might later find discriminatory. The commenters sought clarification on how OCR will handle cases involving health plans regulated by multiple authorities, and suggested that a “deeming” approach would reduce confusion and avoid duplication of costs and administrative effort. Other commenters asked that compliance with language access standards promulgated by CMS or the States be deemed compliance with the final rule; those comments are discussed in more detail in the preamble at § 92.201.

OCR recognizes the efficiencies inherent in harmonizing regulations to which covered entities are subject under various laws. Indeed, entities covered under Section 1557 are likely also subject to a host of other laws and regulations, including CMS regulations, the Genetic Information Nondiscrimination Act of 2008,³ the Family and Medical Leave Act, the ADA, Title VII of the Civil Rights Act of 1964, and State laws. OCR will coordinate as appropriate with other Federal agencies to avoid inconsistency and duplication in enforcement efforts.

That said, OCR declines to adopt a deeming approach whereby compliance with another set of laws or regulations automatically constitutes compliance with Section 1557. As to State laws, it

³ Public Law 110-233, 122 Stat. 881 (2008).

is inappropriate to define requirements under Federal law based on what could be the varying, and potentially changing, requirements of different States' approaches. As to other Federal laws, OCR will give consideration to an entity's compliance with the requirements of other Federal laws where those requirements overlap with Section 1557. In such cases, OCR will work closely with covered entities where compliance with this final rule requires additional steps. But in the final analysis, OCR must, in its capacity as the lead enforcement agency for Section 1557, maintain the discretion to evaluate an entity's compliance with the standards set by the final rule. This is consistent with the approach taken by other agencies to civil rights obligations, in which compliance with one set of requirements, adopted under different laws or for different purposes, is not considered automatic compliance with civil rights obligations.

Subpart A—General Provisions

Purpose and Effective Date (§ 92.1)

In § 92.1, we proposed that the purpose of this part is to implement Section 1557 of the ACA, which prohibits discrimination in certain health programs and activities on the grounds prohibited under Title VI, Title IX, the Age Act, and Section 504, which together prohibit discrimination on the basis of race, color, national origin, sex, age, or disability.

We also proposed that the effective date of the Section 1557 implementing regulation shall be 60 days after the publication of the final rule in the **Federal Register**.

The comments and our responses regarding the proposed effective date are set forth below.

Comment: Some commenters asserted that 60 days after publication of the final rule did not allow sufficient time for entities to come into compliance with Section 1557 and requested that the effective date be one year after publication of the final rule. Similarly, one commenter stated that State agencies covered by Section 1557 need at least 150 days to come into compliance with Section 1557. The commenter stated that State agencies need additional time to assess the impacts, align nondiscrimination requirements from multiple Federal agencies, and make the required policy, operational, and system changes.

Response: OCR does not believe that extending the effective date beyond 60 days is warranted, except with regard to specific provisions for which there is a later applicability date, as set forth

below. Most of the requirements of Section 1557 are not new to covered entities, and 60 days should be sufficient to come into compliance with any new requirements.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.1 with one modification. We recognize that some covered entities will have to make changes to their health insurance coverage or other health coverage to bring that coverage into compliance with this final rule. We are sensitive to the difficulties that making changes in the middle of a plan year could pose for some covered entities and are committed to working with covered entities to ensure that they can comply with the final rule without causing excessive disruption for the current plan year. Consequently, to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

Application (§ 92.2)

Section 92.2 of the proposed rule stated that Section 1557 applies to all health programs and activities, any part of which receives Federal financial assistance from any Federal agency. It also stated that Section 1557 applies to all programs and activities that are administered by an Executive Agency or any entity established under Title I of the ACA.

In paragraph (a), we proposed to apply the proposed rule, except as otherwise provided in § 92.2, to: (1) All health programs and activities, any part of which receives Federal financial assistance administered by HHS; (2) health programs and activities administered by the Department, including the Federally-facilitated Marketplaces; and (3) health programs and activities administered by entities established under Title I of the ACA, including the State-based Marketplaces.

In paragraph (b), we proposed limitations to the application of the final rule. We proposed the adoption of the existing limitations and exceptions that already, under the statutes referenced in Section 1557, govern the health

programs and activities subject to Section 1557. We noted that these limitations and exceptions are found in the Age Act and in the regulations implementing the Age Act, Section 504, and Title VI, which apply to all programs and activities that receive Federal financial assistance.

In paragraph (b)(1), we proposed to incorporate the exclusions found in the Age Act, such that the provisions of the proposed rule would not apply to any age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which provides any benefits or assistance to persons based on age, establishes criteria for participation in age-related terms, or describes intended beneficiaries to target groups in age-related terms.⁴ We requested comment on whether the exemptions found in Title IX and its implementing regulation should be incorporated into the final rule. We noted that unlike the Age Act, Section 504, and Title VI, which apply to all programs and activities that receive Federal financial assistance (including health programs and activities), Title IX applies only in the context of education programs and not to the majority of the health programs and activities subject to the proposed rule. In addition, we noted that many of Title IX's limitations and exceptions do not readily apply in a context that is grounded in health care, rather than education.

We invited comment on whether the regulation should include any specific exemptions for health service providers, health plans, or other covered entities with respect to requirements of the proposed rule related to sex discrimination. We stated that we wanted to ensure that the proposed rule had the proper scope and appropriately protected sincerely held religious beliefs to the extent that those beliefs may conflict with provisions of the proposed regulation. We noted that certain protections already exist with respect to religious beliefs, particularly with respect to the provision of certain health-related services; for example, we noted that the proposed rule would not displace the protections afforded by provider conscience laws,⁵ the Religious Freedom Restoration Act (RFRA),⁶ provisions in the ACA related to abortion services,⁷ or regulations issued

⁴ See 42 U.S.C. 6103(b).

⁵ See, e.g., 42 U.S.C. 300a-7; 42 U.S.C. 238n; Consolidated and Further Continuing Appropriations Act 2015, Public Law 114-53, Div. G, § 507(d) (Dec. 16, 2015).

⁶ 42 U.S.C. 2000bb-1.

⁷ See, e.g., 42 U.S.C. 18023.

under the ACA related to preventive health services.⁸ We invited comment on the extent to which these existing protections provide sufficient safeguards for any religious concerns in applying Section 1557.

We noted that a fundamental purpose of the ACA is to ensure that health services are available broadly on a nondiscriminatory basis to individuals throughout the country. Thus, we requested comment on any health care consequences that would ensue were the regulation to provide additional exemptions.

We also requested comment on the scope of additional exemptions, if any, that should be included and the processes for claiming them, including whether those processes should track those used under Title IX, at 45 CFR 86.12.

The comments and our responses regarding § 92.2 are set forth below.

Comment: Some commenters recommended that the final rule apply not only to health programs and activities receiving Federal financial assistance from the Department, but to health programs and activities receiving Federal financial assistance from other Departments. The commenters noted that in enacting Section 1557, Congress delegated rulemaking authority to the Department; they therefore maintained that the Department has the authority to promulgate rules that apply to other Departments. Commenters further noted that the Department has greater expertise in the application of civil rights laws to health programs and activities than do other Departments, and further urged that HHS regulations applicable to health programs and activities receiving Federal financial assistance from other Departments would be afforded deference under *Chevron U.S.A. v. NRDC, Inc.*⁹

In the alternative, commenters recommended that we collaborate with other Departments to effectuate the provisions of the final rule and ensure that other Departments enter into delegation agreements or Memoranda of Understanding that grant HHS interpretation and enforcement authority over health programs funded and administered by other Departments or that commit other Departments to move quickly to engage in their own rulemaking on Section 1557.

Response: While the rule recognizes that Section 1557 itself applies to health programs and activities receiving Federal financial assistance from other Departments, we decline to extend the

scope of the rule to health programs and activities receiving Federal financial assistance from other Departments. Drafting a rule applicable to health programs and activities assisted by other Departments would pose numerous challenges, one of which is that the Department lacks the information and expertise necessary to apply the rule to those programs without further engagement and collaboration with those Departments. We agree that expeditious implementation of Section 1557 by other Departments is desirable, and hope that the Department's final rule will inform enforcement of Section 1557 by other Departments with respect to their federally assisted health programs and activities. To this end, the OCR Director sent a memorandum encouraging coordination of enforcement responsibilities under Section 1557 to all Federal agencies in November 2015.

Comment: Commenters recommended that the final rule apply not just to programs administered by HHS, but also to programs administered by other Departments.

Response: We decline to make the rule applicable to programs administered by other Departments. We will, however, continue to work with other Departments that administer health programs and activities to help those Departments ensure that their programs are nondiscriminatory.

Comment: Many commenters responded to the proposed rule's request for comment on whether the rule should include a religious exemption for health care providers, health plans, or other covered entities with respect to the requirements of the rule related to sex discrimination, or whether existing protections, including RFRA, ACA regulations for preventive health services, and Federal provider conscience laws provide sufficient safeguards for religious concerns.

Most of the organizations that commented on this issue, including professional medical associations and civil rights organizations, and the overwhelming majority of individual commenters, many of whom identified themselves as religious, opposed any religious exemption on the basis that it would potentially allow for discrimination on the bases prohibited by Section 1557 or for the denial of health services to women. Several religious organizations also opposed a religious exemption, asserting that RFRA, the Federal provider conscience statutes, and State RFRA statutes, which many States have enacted, provide sufficiently strong protections for religious providers and institutions.

Many commenters said that mergers of religiously-affiliated hospitals with other hospitals have deepened concerns that would be raised by providing a religious exemption, as the mergers may leave individuals in many communities with fewer health care options offering the full range of women's health services. Many commenters also pointed to the language in the majority opinion in the Supreme Court's decision in *Hobby Lobby v. Burwell* that RFRA is not a shield that permits discrimination "cloaked as religious practice to escape legal sanction."¹⁰

Some religious organizations that submitted comments strongly supported a religious exemption, arguing that faith-based health care providers and employers would be substantially burdened if required to provide or refer for, or purchase insurance covering, particular services such as gender transition services. Supporters of an exemption recommended that Section 1557 incorporate the religious exemption in Title IX, which exempts educational institutions controlled by religious organizations from the prohibition of sex discrimination if the application would be inconsistent with the religious tenets of the organization.¹¹ None of the commenters supporting a religious exemption asserted that there would be a religious basis for generally refusing to treat LGBT individuals for a medical condition, for example, refusing to treat a broken bone or cancer; rather, commenters asserted that the rule should exempt faith-based providers from providing particular services, such as services related to gender transition, that are inconsistent with their religious beliefs.

Response: As noted in the preamble to the proposed rule, certain protections already exist in Federal law with respect to religious beliefs, particularly with regard to the provision of certain health-related services. For example, we noted that the proposed rule would not displace the protections afforded by provider conscience laws,¹² RFRA,¹³ provisions in the ACA related to abortion services,¹⁴ or regulations issued under the ACA related to preventive health services.¹⁵ Nothing in

¹⁰ 132 S. Ct. 2751, 2783 (2014).

¹¹ 20 U.S.C. 1681(a)(3).

¹² See, e.g., 42 U.S.C. 300a-7; 42 U.S.C. 238n; Consolidated and Further Continuing Appropriations Act 2015, Pub. L. 114-53, Div. G, § 507(d) (Dec. 16, 2015).

¹³ 42 U.S.C. 2000bb-1.

¹⁴ See, e.g., 42 U.S.C. 18023.

¹⁵ See 45 CFR 147.131.

⁸ See 45 CFR 147.131.

⁹ 467 U.S. 837 (1984).

this final rule displaces those protections.

Although some commenters urged us also to incorporate Title IX's blanket religious exemption into this final rule, we believe that applying the protections in the laws identified above offers the best and most appropriate approach for resolving any conflicts between religious beliefs and Section 1557 requirements. With regard to abortion, for example, specific ACA provisions concerning abortion will continue to control, including, but not limited to, provisions that bar qualified health plans offered through a MarketplaceSM 16 from discriminating against an individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions,¹⁷ and provisions that state that nothing in the ACA shall be construed to require a qualified health plan to provide coverage of abortion as an essential health benefit.¹⁸

In other cases, application of RFRA is the proper means to evaluate any religious concerns about the application of Section 1557 requirements. The RFRA analysis evaluates whether a legal requirement substantially burdens the exercise of religion; if so, the question becomes whether the legal requirement furthers a compelling interest and is the least restrictive means to further that interest.

We believe that the government has a compelling interest in ensuring that individuals have nondiscriminatory access to health care and health coverage and, under RFRA, would assess whether a particular application of Section 1557 substantially burdened a covered entity's exercise of religion and, if so, whether there were less restrictive alternatives available. Claims under RFRA are individualized and fact specific and we would make these determinations on a case-by-case basis, based on a thorough analysis and relying on the extensive case law interpreting RFRA standards.

We decline to adopt commenters' suggestion that we import Title IX's blanket religious exemption¹⁹ into Section 1557. Section 1557 itself contains no religious exemption. In addition, Title IX and its exemption are limited in scope to educational institutions, and there are significant differences between the educational and

health care contexts that warrant different approaches.

First, students or parents selecting religious educational institutions typically do so as a matter of choice; a student can attend public school (if K–12) or choose a different college. In the health care context, by contrast, individuals may have limited or no choice of providers, particularly in rural areas or where hospitals have merged with or are run by religious institutions. Moreover, the choice of providers may be even further circumscribed in emergency circumstances.

Second, a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results. Thus, it is appropriate to adopt a more nuanced approach in the health care context, rather than the blanket religious exemption applied for educational institutions under Title IX.

Based on the foregoing, we have included a provision in this final regulation making clear that where application of this regulation would violate applicable Federal statutory protections for religious freedom and conscience, that application will not be required. The Department also retains the discretion to provide other accommodations or exemptions where permitted by Federal law and supported by sound public policy.

Comment: One commenter suggested that we clarify that the regulation applies only to a covered entity's health operations "in the United States."

Response: This regulation applies only to individuals who are subjected to discrimination, at least in part, in the United States and to the provision or administration of health-related services or health-related insurance coverage in the United States, consistent with the four statutes referenced in Section 1557.²⁰

Consistent with the Department's Title VI regulation,²¹ OCR interprets "United States" to include the U.S. territories. The definition of "recipient" of Federal financial assistance in the civil rights laws referenced in Section 1557 does not contain geographic limitations, and includes, in addition to States and political subdivisions, other "public or private agenc[ies], institution[s], or organization[s]." ²² Thus, health programs and activities of

the U.S. Territories, and those provided or administered in the U.S. Territories, are covered by the final rule.²³

Comment: One commenter requested that we clarify that expatriate health plans, plan sponsors of self-funded expatriate health plans, and issuers of fully-insured expatriate health plans are exempt from Section 1557 pursuant to the Expatriate Health Coverage Clarification Act of 2014 (EHCCA),²⁴ which provides generally that provisions of the ACA do not apply to expatriate health plans, employer plan sponsors of expatriate health plans, or expatriate health insurance issuers. The commenter noted that the EHCCA does not include any exceptions or special rules pertaining to Section 1557; thus, the commenter asserted, applying Section 1557 to expatriate health plans would be contrary to Congressional intent and would competitively disadvantage American health issuers in the global marketplace, resulting in consumers choosing offshore options and American issuers moving their plans offshore to compete.

Response: Section 3(a)²⁵ of the EHCCA specifies that the provisions of (including any amendment made by) the ACA and Title I and subtitle B of Title II of the Health Care and Education Reconciliation Act of 2010 shall not apply with respect to expatriate health plans; employers with respect to such plans, solely in their capacity as plan sponsors for such plans; or expatriate health insurance issuers with respect to coverage offered by such issuers under such plans, subject to the exceptions and special rules enumerated in Sections 3(B) and 3(C) of the EHCCA. Section 1557 is contained in Title I of the ACA; thus, pursuant to the EHCCA, Section 1557 does not apply with respect to expatriate health plans, expatriate health insurance issuers, or employer plan sponsors of expatriate plans, as defined in the EHCCA.

Comment: Tribes and tribal organizations submitted comments recommending that we make a number of changes throughout the rule and preamble to address the application of the rule to tribes and tribal health programs. Commenters objected to the characterization of 45 CFR 80.3(d), the exception in the Title VI regulation for

¹⁶ Health Insurance MarketplaceSM and MarketplaceSM are service marks of the U.S. Department of Health and Human Services.

¹⁷ 42 U.S.C. 18023(b)(4).

¹⁸ 42 U.S.C. 18023(b)(1)(A).

¹⁹ 42 U.S.C. 18116(a).

²⁰ 20 U.S.C. 1681(a); 29 U.S.C. 794(a); 42 U.S.C. 2000d; 42 U.S.C. 6102.

²¹ 45 CFR 80.13(e).

²² 45 CFR 80.13(i) (Title VI); 84.3(f) (Section 504); 86.2(i) (Title IX); 90.4 (Age Act).

²³ OCR notes that in contrast to Section 1557, which does not refer to the United States or to "states," other ACA provisions refer to "states" and the Department has interpreted the meaning of "state" in the context of those statutory requirements. See 45 CFR 144.103.

²⁴ Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113–235, Div. M, § 3 (codified at 42 U.S.C. 18014).

²⁵ 42 U.S.C. 18014(f).

Indian health programs and other programs limited by Federal law to individuals of a particular race, color, or national origin, that has been incorporated into the Section 1557 rule, and recommended that we refer to 45 CFR 80.3(d) throughout and describe it rather than simply cite to it. Commenters asked us to exempt tribes and tribal health programs from § 92.207 and § 92.208 and make clear that tribal governments and health programs can limit insurance to their members. Commenters asserted that Purchased/Referred Care²⁶ programs should be permitted to limit coverage and be held harmless for discrimination on the basis of disability, age, or sex. One commenter recommended several additional changes to the rule to address its application to tribes, including excluding tribes and tribal health programs from the definitions of “covered entity” and “health program or activity,” and excluding assistance to tribes and tribal health programs from the definition of “Federal financial assistance,” along with other changes intended to achieve this purpose. Commenters stated that the changes proposed were necessary to reflect the full scope of protections in Federal law for tribal classifications and tribal sovereignty.

Response: 45 CFR 80.3(d) is not an exemption from coverage; it provides an exception to application of the prohibitions on race, color, and national origin discrimination when programs are authorized by Federal law to be restricted to a particular race, color, or national origin. The final rule incorporates that exception, and OCR will fully apply it, as well as other exemptions or defenses that may exist under Federal law. OCR intends to address any restrictions on application of the law to tribes in the context of individual complaints.

Comment: One tribal organization commented that tribal consultation on development of the rule was insufficient.

Response: We engaged in tribal consultation on the rule and, during that consultation, encouraged tribes and tribal organizations to submit comments on the proposed rule. Many did so. We believe that tribal consultation was sufficient.

Comment: One tribal organization stated that the reference to Indian

Health Services (IHS) programs in the preamble was misleading, as some IHS programs are administered directly by tribes.

Response: We agree that the reference to IHS programs as an example of a federally administered program may be confusing, given that some IHS programs are administered directly by tribes. We have therefore changed the reference to “IHS programs” to “IHS programs administered by IHS.”

Finally, we have added a severability clause to § 92.2, to indicate our intention that the rule be construed to give the maximum effect permitted by law to each provision. The rule provides that if a provision is held to be unenforceable in one set of circumstances, it should be construed to give maximum effect to the provision as applied to other persons or circumstances. Similarly, if a provision is held to be invalid or unenforceable, that provision should be severable from, and have no impact on the application of, the remainder of the rule. This provision is consistent with our interpretation of the Department’s regulations implementing Title VI, Title IX, Section 504, and the Age Act.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.2, with two modifications. We are adding § 92.2(b)(2), which clarifies that if an application of Section 1557 requirements or this part would violate applicable Federal statutory protections for religious freedom and conscience, application of Section 1557 is not required. In addition, we have added § 92.2(c), containing a severability clause.

Relationship to Other Laws (§ 92.3)

In § 92.3 of the proposed rule, we proposed an explanation of the relationship of the rule to existing laws. Paragraph (a) proposed that Section 1557 is not intended to apply lesser standards for the protection of individuals from discrimination than the standards under Title VI, Title IX, Section 504, the Age Act, or the regulations issued pursuant to those laws. Consistent with the statute, paragraph (b) proposed that nothing in this part shall be interpreted to invalidate or limit the existing rights, remedies, procedures, or legal standards available to individuals aggrieved under other Federal civil rights laws or to supersede State or local laws that provide greater or equal protection against discrimination on the basis of

race, color, national origin, sex, age, or disability. OCR explained that this intent is derived from Section 1557(b) of the ACA. In addition to the statutes that are cited directly in Section 1557(b), the proposed rule cited the Architectural Barriers Act of 1968,²⁷ the Americans with Disabilities Act of 1990 (ADA),²⁸ and Section 508 of the Rehabilitation Act of 1973 (Section 508).²⁹ We noted that these laws establish additional Federal civil rights protections for individuals with disabilities, and covered entities must be mindful that the obligations imposed by those laws apply to them independent of the application of Section 1557.

Summary of Regulatory Changes

OCR did not receive any comments on this provision. Therefore, for the reasons set forth in the proposed rule, we are finalizing the provisions as proposed in § 92.3 without modification.

Definitions (§ 92.4)

In § 92.4 of the proposed rule, we set out proposed definitions of various terms. The comments and our responses regarding § 92.4 are set forth below.

Disability. We proposed that the definition of “disability” be the same as the definition of this term in the Rehabilitation Act,³⁰ which incorporates the definition of disability in the ADA, as construed by the ADA Amendments Act of 2008.³¹ In addition, we proposed to use the term “disability” in place of the term “handicap,” which is used in some previous civil rights statutes and regulations. We provided that when we cross-reference other regulatory provisions, regulatory language that uses the term “handicap” shall mean “disability.” We noted that this change in terminology does not reflect a change in the substance of the definition.

Comment: OCR received many comments related to the definition of disability. Several commenters asked OCR to provide additional guidance regarding the meaning of terms used within the definition of disability, including “physical or mental impairment,” “major life activities,” and “substantially limits.” Other commenters asked OCR to include the term “chronic conditions” in the definition of disability or to add

²⁷ 42 U.S.C. 4151–4157 (2012).

²⁸ 42 U.S.C. 12101 *et seq.* (codified as amended by the Americans with Disabilities Amendments Act of 2008, Public Law 110–325, 122 Stat. 3553 (2008)).

²⁹ 29 U.S.C. 794d.

³⁰ 29 U.S.C. 705(9)(B).

³¹ Public Law 110–325, 122 Stat. 3553, § 4 (Sept. 25, 2008) (codified at 42 U.S.C. 12102).

²⁶ Funds under the Purchased/Referred Care program (formerly the Contract Health Services program) are used to supplement and complement other health care resources available to eligible American Indians and Alaska Natives. See <https://www.ihs.gov/newsroom/index.cfm/factsheets/purchasedreferredcare> (last updated Jan. 2015).

regulatory language to the definition of disability that creates a rebuttable presumption of disability for serious and chronic conditions. Still other commenters urged that OCR clarify that the definitions of disability and qualified individual with a disability are broad.

Response: As noted in the proposed rule, the definition of “disability” is the same as the definition of this term in the Rehabilitation Act, which incorporates the definition of disability in the ADA, as construed by the ADA Amendments Act of 2008. Thus, the proposed rule incorporates the definition of “major life activities” and the construction of all of the terms and standards in the definition of “disability” set forth in the ADA Amendments Act. We believe this definition is appropriate and that OCR’s intent, consistent with the ADA Amendments Act, to broadly interpret the term “disability” is clear. Whether a chronic condition is a disability will depend on whether it falls within the definition of disability in the final rule.

Comment: A few commenters asked for a definition of the term “reasonable modification.” Other commenters asked for a definition of “accessibility,” especially as that term pertains to electronic and information technology. Both sets of commenters suggested that adding definitions to the final rule would provide greater clarity to covered entities.

Response: OCR believes that defining the terms “reasonable modification” and “accessibility” in this rule is unnecessary, given the meaning that these terms have acquired in the long history of enforcement of Section 504 and the ADA in the courts and administratively. We intend to interpret both terms consistent with the way that we have interpreted these terms in our enforcement of Section 504 and the ADA and so decline to add these definitions to the final rule.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition of “disability” as proposed without modification.

Electronic and information technology. We proposed to define “electronic and information technology” to be consistent with 36 CFR 1194.4, the regulation implementing Section 508.

Comment: A few commenters recommended that OCR amend the definition of “electronic and information technology” to state that “electronic and information technology includes hardware, software, integrated

technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.” These commenters asserted that this definition, which is based on the definition of “health information technology” in the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009,³² is preferable to the definition OCR proposed, which is based on the regulations implementing Section 508 that were promulgated in 2000.

According to these commenters, the Section 508 definition is outdated and unduly narrow.

Response: As OCR stated in the Notice of Proposed Rulemaking, the definition of “electronic and information technology” is based on 36 CFR 1194.4, the regulation implementing Section 508. OCR believes that a definition of “electronic and information technology” that is consistent with the regulations implementing Section 508 will reduce the possibility of confusing or conflicting standards for covered entities. Moreover, the definition used in the HITECH Act was created for use in another context and is narrower in some respects than would be appropriate for Section 1557. However, OCR also shares the commenters’ concern that the current definition found at 36 CFR 1194.4 is outdated and unduly narrow. Accordingly, OCR notes the recent Access Board proposal to replace the term “electronic and information technology” with an updated term and definition.

Specifically, on February 27, 2015, the Access Board proposed to revise and update its standards for electronic and information technology developed, procured, maintained, or used by Federal agencies covered by Section 508.³³ As part of these proposed revisions and updates, the Access Board announced that it intends to replace the term “electronic and information technology” in 36 CFR 1194.4 with the term “information and communication technology” and revise the definition significantly to make it broader and more compatible with modern technology.³⁴ OCR believes that the changes proposed by the Access Board

will address the commenters’ concerns. Therefore, and in order to maintain consistency with Section 508 while also addressing commenters’ concerns that the definition proposed by OCR is outdated and unduly narrow, OCR has decided to change the definition of “electronic and information technology” in this rule so that it means the same as “electronic and information technology” as defined at 36 CFR 1194.4 or any term that replaces “electronic and information technology” at 36 CFR 1194.4. By citing to the regulation, OCR’s definition will update with the Access Board’s finalized rule.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we have changed the definition of “electronic and information technology” as proposed in § 92.4 to state that it means the same as “electronic and information technology,” or any term that replaces it at 36 CFR 1194.4.

Employee health benefit program. We proposed that the term “employee health benefit program” means (1) health benefits coverage or health insurance provided to employees and/or their dependents established, operated, sponsored or administered by, for, or on behalf of one or more employers, whether provided or administered by entities including but not limited to a health insurance issuer, group health plan (as defined in the Employee Retirement Income Security Act of 1974 (ERISA), at 29 U.S.C. 1191b(a)), a third party administrator, or an employer; (2) an employer-provided or -sponsored wellness program; (3) an employer-provided health clinic; or (4) long term care coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer for a covered entity’s employees.

Comment: One commenter requested that OCR clarify that wellness programs that are separate from the employee health benefit plan are still an “employee health benefit program.”

Response: We agree that wellness programs separate from an employee health benefit plan fall within the definition of an employee health benefit program. For example, an employer providing a gift card to each employee who receives a flu shot would be a wellness program within the meaning of the regulation, regardless of whether the wellness program is part of the employer’s group health plan. We believe that the definition of “employee health benefit program” in the

³² 42 U.S.C. 300jj(5).

³³ Architectural and Transportation Barriers Compliance Board, Information and Communication Technology (ICT) Standards and Guidelines. 80 FR 10880 (proposed Feb. 27, 2015) (to be codified at 36 FR pt. 1194).

³⁴ See 80 FR at 10905.

regulation makes this clear and thus are not adopting any revisions.

Comment: Some commenters requested that the definition of “employee health benefit program” specifically include excepted benefits, as defined for purposes of section 2791(c) of the Public Health Service Act (codified at 42 U.S.C. 300gg–91(c)), such as limited scope vision and dental insurance, disease-specific insurance and fixed-indemnity plans.

Response: We do not believe it is necessary to include an exhaustive list of types of benefits that would be included as an “employee health benefit program.” The definition is broad enough to encompass any health benefit coverage or health insurance provided by an employer to its employees. Excepted benefits are further discussed infra under § 92.207.³⁵

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 with minor technical revisions for clarity and for consistency with other parts of the final rule. We are making minor technical corrections to correct the ERISA citation to read “29 U.S.C. 1191b(a)(1)”; to clarify that the term “sponsored wellness program” is an “employer-sponsored” wellness program; to add “coverage” to the term “health insurance”; and to clarify that long term care coverage or insurance is provided or administered “for the benefit of an employer’s employees.”

Federal financial assistance. We proposed that the term “Federal financial assistance” includes grants, loans, and other types of assistance in accordance with the definition of “Federal financial assistance” in the regulations implementing Section 504³⁶ and the Age Act,³⁷ and also specifically includes subsidies and contracts of insurance, in accordance with the statutory language of Section 1557. We also proposed that, consistent with OCR’s enforcement of other civil rights authorities, the definition of Federal financial assistance does not include Medicare Part B.

An additional clause was added to the proposed regulatory provision, modeled on the definition of “Federal financial assistance” in the regulation implementing Title IX, which clarifies that in the educational context, Federal financial assistance includes wages,

loans, grants, scholarships and other monies that are given to any entity for payment to or on behalf of students who are admitted to that entity or that are given directly to these students for payment to that entity.³⁸ In the proposed rule, we noted that in the health care context, Federal funds are provided to or on behalf of eligible individuals for premium tax credits and advance payments of premium tax credits and cost sharing reductions to ensure the affordability of health insurance coverage purchased through the Health Insurance Marketplaces. Thus, we noted that an issuer participating in any Health Insurance MarketplaceSM is receiving Federal financial assistance when advance payments of premium tax credits and/or cost sharing reductions are provided to or on behalf of any of the issuer’s enrollees. We noted that a health care provider that contracts with such an issuer does not become a recipient of Federal financial assistance by virtue of the contract, but would be a recipient if the provider otherwise receives Federal financial assistance.

Comment: Many commenters objected to the statement in the preamble to the proposed rule that, consistent with OCR’s enforcement of other civil rights authorities, the definition of Federal financial assistance does not include Medicare Part B. These commenters urged us to reverse this position, asserting that the historical rationale for the Department’s position that Medicare Part B payments are not Federal financial assistance is inapplicable to Section 1557, which explicitly covers “contracts of insurance,” and inconsistent with the current Medicare Part B payment scheme, in which providers are paid directly by the Medicare program instead of receiving payment from consumers who are then reimbursed by the Medicare program.

Response: OCR notes commenters’ concerns, but does not believe that this rule is the appropriate vehicle to modify the Department’s position.

Comment: We received many comments proposing that OCR revise the statement that a health care provider that contracts with an issuer does not become a recipient of Federal financial assistance by virtue of the contract. Commenters proposed that such a provider should become a recipient, and thus be covered by Section 1557, by virtue of the contract. The commenters expressed concern that under OCR’s interpretation, such contractors would not be covered by the nondiscrimination

requirements of Section 1557, thereby weakening the rule’s effect.

Response: We do not believe the law supports the commenters’ proposed across-the-board revision. Under the regulations implementing the statutes cited in Section 1557 and incorporated into this final rule, a recipient of Federal financial assistance is an entity to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient. To determine whether an entity is a recipient of such assistance, courts look to the entity that Congress intended to assist or subsidize with those funds.³⁹ In this context, the contractor that is providing health services is not the intended recipient of a premium tax credit or cost-sharing reduction that an issuer receives and is therefore not covered under Section 1557 by virtue of the contract.

That said, there are numerous ways in which health services providers are recipients in their own right, whether the Federal financial assistance they receive comes through certain Medicare payments, Medicaid payments, or other funds from the Department. Therefore, instead of falling outside of Section 1557’s purview, many health care providers will be subject to Section 1557 irrespective of their relationship to issuers receiving Federal financial assistance.

Moreover, nothing in the rule authorizes qualified health plan issuers or other issuers that are covered entities to contract away their own nondiscrimination obligations. Issuers must ensure that enrollees have equal access to health services provided by their coverage without discrimination on the basis of a prohibited criterion. Thus, even if individual providers do not independently receive Federal financial assistance, an issuer maintains a duty to ensure compliance with civil rights laws with respect to the treatment of its enrollees who use its networks.

Comment: One comment inquired whether the rule applies to programs in which the Department is an employer or when the Department offers benefits to Department employees.

Response: The Department is not covered as a federally assisted program, although the Department is covered by the rule as an administrator of health programs and activities. As to programs for Department employees, HHS is covered by employment discrimination laws, including Section 504 and Title VII, protecting Federal employees.

³⁵ See *infra* discussion of excepted benefits under § 92.207.

³⁶ 45 CFR 84.3(h).

³⁷ 45 CFR 91.4.

³⁸ See 45 CFR 86.2(g)(1)(ii).

³⁹ *United States Dep’t of Transport. v. Paralyzed Veterans of Amer.*, 477 U.S. 597, 604–06 (1986).

Comment: One commenter raised concerns over the applicability of the rule to doctors in solo medical practice, to doctors who practice in many settings, and to medical students receiving student loans. The commenter suggested that the health program or activity—not the solo practitioner as an individual—be required to comply with the rule, and requested that we clarify how a doctor can determine whether she is covered by the rule as she moves between practice settings. The commenter also expressed concern that a disproportionate number of younger doctors would be required to comply with the rule as recipients of Federal financial assistance in the form of student loans.

Response: We have not modified the final rule in response to these comments; however, we offer the following for clarification.

Section 1557 applies to a recipient of Federal financial assistance, whether a hospital, clinic, medical practice, or individual physician. Where, for example, a doctor is an employee of a hospital and the hospital receives Federal financial assistance, the hospital's program is the relevant health program or activity and it is the hospital that will be held accountable for discrimination under Section 1557. Where, similarly, a doctor contracts as an individual to provide health services at a free neighborhood clinic that receives Federal financial assistance, the clinic is the recipient of Federal financial assistance and liable for discrimination; the doctor is simply a contractor who is assisting the clinic in performing clinic services.

When a doctor has a private medical practice that receives Federal financial assistance, and the doctor, through her practice, works as an attending physician at a hospital, it is the medical practice that is providing the services at the hospital, and thus the practice that is liable for the discrimination.⁴⁰ Moreover, a solo medical practice (whether incorporated or not) that receives Federal financial assistance is a covered health program or activity.⁴¹

This approach is consistent with longstanding interpretations of civil rights law and the definition of a "recipient" of Federal financial assistance in the regulations implementing Section 504, Title VI, Title IX and the Age Act.

⁴⁰ The hospital may also be responsible for discrimination by the doctor's practice that occurs at the hospital.

⁴¹ The rule defines a "recipient" of Federal financial assistance to include an individual. See § 92.4.

Finally, regarding receipt of student loan payments as Federal financial assistance, we clarify that the educational institution—not the student—is the recipient of the Federal financial assistance in that circumstance. Although the money is paid directly to the student, the university or other educational institution is the intended recipient. This is consistent with longstanding regulations implementing civil rights laws.

We made two clarifying changes to the definition of Federal financial assistance. In the proposed rule, we defined Federal financial assistance in subsection (1) as any type of arrangement in which the Federal government "provides or makes available" assistance. In subsection (2), we explained that Federal financial assistance "provided or administered by the Department" includes tax credits and other subsidies under Title I of the ACA and other funds providing health insurance coverage. Because our intention was to explain further the meaning of (1) as it applies to the Department in (2), we have changed (2) to use the same terms used in (1). Thus, (2) now refers to Federal financial assistance "provided or made available" by the Department.

In addition, in the proposed rule, subsection (2) provided that "Federal financial assistance provided or administered by the Department includes all tax credits under Title I of the ACA," as well as other funds extended by the Department for providing health coverage. Because the Department plays a role in administering tax credits under Title I of ACA but does not have primary responsibility for administering that credit, and to ensure that tax credits under Title I of the ACA are understood to be included within the definition, we have modified this subsection to state that Federal financial assistance the Department provides or makes available includes Federal financial assistance that the Department plays a role in providing or administering.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 with two modifications. The language of Subsection (2) of the definition has been modified to state that Federal financial assistance the Department provides or makes available includes Federal financial assistance that the Department plays a role in providing or administering.

Gender identity. We proposed that the term "gender identity" means an individual's internal sense of gender, which may be different from an individual's sex assigned at birth. We noted that the way an individual expresses gender identity is frequently called "gender expression," and may or may not conform to stereotypes associated with a particular gender. We also noted in the proposed rule that gender may be expressed through, for example, dress, grooming, mannerisms, speech patterns, and social interactions. For purposes of this part, we proposed that an individual has a transgender identity when the individual's gender identity is different from the sex assigned to that person at birth; an individual with a transgender identity is referred to in this part as a transgender individual. In the proposed rule, we noted that the approach taken in the proposed definition is consistent with the approach taken by the Federal government in similar matters.⁴²

Comment: Several commenters suggested that we revise the definition of "gender identity" to reference non-binary identities in order to avoid ambiguity regarding application of the rule to individuals with non-binary gender identities. Some commenters noted that explicitly referencing non-binary identities in this definition would be important to avoid any doubt or misinterpretation given that gender has often been assumed to be binary, thus ignoring or marginalizing individuals with non-binary gender identities.

Response: OCR has made a slight change to the definition of "gender identity" to insert the clause "which may be male, female, neither, or a combination of male and female." The insertion of this clause helps clarify that those individuals with non-binary gender identities are protected under the rule.

Comment: Some commenters suggested that, consistent with previous court and Federal agencies' interpretations, OCR add "gender expression" to the definition of "gender identity" in order to make explicit our

⁴² See, e.g., U.S. Office of Personnel Management, Guidance Regarding the Employment of Transgender Individuals in the Federal Workplace (May 27, 2011), <https://www.opm.gov/policy-data-oversight/diversity-and-inclusion/reference-materials/gender-identity-Guidance/>; U.S. Office of Personnel Management, U.S. Equal Employment Opportunity Commission, U.S. Office of Special Counsel, U.S. Merit Systems Protection Board, Addressing Sexual Orientation and Gender Identity Discrimination in Federal Civilian Employment: A Guide to Employment Rights, Protections, and Responsibilities, p. 2 (June 2015), <http://www.opm.gov/LGBTGuide>.

intention to protect individuals on this basis.

Response: In the proposed and final rules' definition of gender identity, we explain that the way an individual expresses gender identity is frequently called "gender expression." OCR is clarifying that throughout this final rule, we interpret references to the term "gender identity" as encompassing "gender expression" and "transgender status." This position is consistent with the position taken by courts and Federal agencies.⁴³ These bases of discrimination are protected under the rule.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with three modifications. The first sentence of the definition of gender identity has been revised to reference the application of the rule to individuals with non-binary gender identities. OCR also made a technical edit to the last sentence to delete reference to the term "transgender identity." Finally, for clarity and consistency within the final rule, OCR has made a technical revision to the definition of gender identity to clarify that a transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.

Health program or activity. We proposed that the term "health program or activity" means the provision or administration of health-related services or health-related insurance coverage and the provision of assistance in obtaining health-related services or health-related insurance coverage. We also proposed that, similar to the approach of the Civil Rights Restoration Act of 1987 (CRRRA)⁴⁴ and except as specifically set forth otherwise in this part,⁴⁵ the term further includes all of the operations of an entity principally engaged in providing or administering health services or health insurance coverage, such as a hospital, health clinic, community health center, group health plan, health insurance issuer, physician's practice, nursing facility, or

residential or community-based treatment facility. We proposed that OCR interpret "principally engaged" in a manner consistent with civil rights laws that use this term.

In the proposed rule, OCR stated that we intended the plural "health programs or activities" used in this part to have the same meaning as the term "health program or activity" in the singular. Similarly, we noted that the proposed part's use of "health programs and activities," a variation of "health program or activity," does not reflect a change in the substance of the definition of "health program or activity."

We proposed to interpret "health programs and activities" to include programs such as health education and health research programs. Because Federal civil rights laws already prohibit discrimination on the basis of race, color, national origin, disability, or age in all health research programs and activities that receive Federal financial assistance and prohibit discrimination on the basis of sex in all health research programs conducted by colleges and universities, we determined that the application of Section 1557 to health research should impose limited additional burden on covered entities.

However, OCR recognized that health research is conducted to answer scientific questions and improve health through the advancement of knowledge; it is not designed to result in direct health benefits to participants. We also recognized that research projects are often limited in scope for many reasons, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other nondiscriminatory considerations. Thus, we noted that criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.⁴⁶ OCR noted that we do not intend for inclusion of health research within the definition of health program or activity to alter the fundamental manner in which research projects are designed, conducted, or funded; nor did OCR propose to systematically review health research protocols.

We invited comment on programs and activities that should be considered health programs or activities.

Comment: We received comments requesting that we enumerate additional

examples of a health program or activity, including but not limited to the Children's Health Insurance Program, all of the operations of Medicare, and student health plans.

Response: We agree that the Children's Health Insurance Program and other health programs operated by State and local governments are covered by the rule. We also agree that student health plans are a health program or activity covered by the rule, and note that all student health plans are covered by Title IX, as well as the other civil rights laws cited in Section 1557, if the institution receives Federal financial assistance.

Although the definition does not and could not specifically identify all health programs and activities covered by the rule (for example, we do not specifically mention programs that provide physical and/or behavioral health services, although they are health programs), we are adding the Children's Health Insurance Program and the Basic Health Program as additional examples, given their significance.

We decline to include "all the operations of Medicare" in the definition of health program or activity. While we agree that all parts of the Medicare program are a health program or activity, not all operations in the Medicare program constitute Federal financial assistance; as discussed above, Medicare Part B is excluded from the definition of Federal financial assistance under this rule and other HHS civil rights authorities.⁴⁷ Thus, we believe the proposed language could create confusion in determining the scope of the final rule.

Comment: Some commenters noted that OCR did not propose to define the term "health" in "health program and activity," and recommended that OCR use the definition of "health" adopted by the World Health Organization, which includes an individual's or population's physical, mental, or social well-being.⁴⁸

Response: OCR declines to add a definition of "health," but interprets "health" to include physical and mental well-being.

Comment: Several commenters recommended that the rule apply only to the specific health program for which the entity receives Federal financial assistance, such as health insurance coverage sold through the MarketplaceSM, and not to other

⁴³ See *Rumble v. Fairview Health Servs.*, Civ. No. 14-cv-2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (Section 1557); *Schroer v. Billington*, 577 F. Supp.2d 293, 303 (D.D.C. 2008) (Title VII); *Macy v. Holder*, EEOC Appeal No. 0120120821, Agency No. ATF-2011-00751, 2012 WL 1435995, at *7 (Apr. 20, 2012), <http://www.eeoc.gov/decisions/0120120821%20Macy%20v%20DOJ%20ATF.txt> (Title VII).

⁴⁴ Public Law 100-259, 102 Stat. 28 (1988).

⁴⁵ Employee health benefits programs are discussed elsewhere in rule. See *infra* discussion of § 92.208.

⁴⁶ We note that it is not permissible for clinical researchers to consider "cost" of accommodating participants with disabilities as a reason to exclude them from participation.

⁴⁷ Medicare Parts A, C, and D all constitute Federal financial assistance. See www.hhs.gov/civil-rights/for-individuals/faqs/what-qualifies-as-federal-financial-assistance/301/index.html.

⁴⁸ See <http://www.who.int/about/definition/en/print.html> (last visited Mar. 11, 2016).

products and services provided outside the MarketplaceSM by issuers participating in the MarketplaceSM. These commenters stated that applying the rule to operations or products that are not the direct recipients of Federal financial assistance conflicts with the plain meaning of Section 1557.

Response: Section 1557 prohibits discrimination under “any health program or activity, any part of which is receiving Federal financial assistance. . . .” By applying the prohibition if “any part” of the health program or activity receives Federal financial assistance, the law provides that the term “health program or activity” must be interpreted in a manner that uniformly covers all of the operations of any entity that receives Federal financial assistance and that is principally engaged in health services, health insurance coverage, or other health coverage, even if only part of the health program or activity receives such assistance. This interpretation serves the central purposes of the ACA, and effectuates Congressional intent, by ensuring that entities principally engaged in health services, health insurance coverage, or other health coverage do not discriminate in any of their programs and activities, thereby enhancing access to services and coverage.

This approach is consistent with the approach Congress adopted in the CRRRA, which amended the four civil rights laws referenced in Section 1557 and defines “program or activity” to mean “all of the operations of . . . an entire corporation, partnership, or other private organization, or an entire sole proprietorship . . . which is principally engaged in the business of providing,” among other things, a range of social and health services. The CRRRA establishes that the entire program or activity is required to comply with the prohibitions on discrimination if any part of the program or activity receives Federal financial assistance. The CRRRA has been consistently applied since its enactment in 1988, and we believe that Congress adopted a similar approach with respect to the scope of health programs and activities covered by Section 1557. If any part of a health care entity receives Federal financial assistance, then all of its programs and activities are subject to the discrimination prohibition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are modifying the definition as proposed in § 92.4 to include the Children’s Health Insurance

Program and the Basic Health Program as additional examples of a health program or activity.

Individual with limited English proficiency. We proposed that the term “individual with limited English proficiency” codify the Department’s longstanding definition reflected in guidance interpreting Title VI’s prohibition of national origin discrimination, entitled Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against Affecting Limited English Proficient Persons⁴⁹ (HHS LEP Guidance). Under the proposed definition, an individual whose primary language for communication is not English is considered an individual with limited English proficiency if the individual has a limited ability to read, write, speak or understand English. Accordingly, we proposed that an individual whose primary language for communication is not English, even if he or she has some ability to speak English, is an individual with limited English proficiency if the individual has a limited ability to read, write, speak or understand English.

Commenters addressing this definition overwhelmingly supported its codification from the HHS LEP Guidance to regulatory text. We did not receive suggested revisions to the wording of this definition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4, without modification.

Language assistance services. OCR proposed that the term “language assistance services” identify types of well-established methods or services used to communicate with individuals with limited English proficiency, including (1) oral language assistance; (2) written translation of documents and Web sites; and (3) taglines. We noted that a covered entity has flexibility to provide language assistance services in-house or through commercially available options. We declined to offer an exhaustive list of available methods. However, we proposed that paragraph (1) identify the following as available methods to communicate orally with individuals with limited English proficiency: Oral interpretation (in-person or remotely)⁵⁰ and direct

communication through the use of bilingual or multilingual staff competent to communicate directly, in non-English languages using any necessary specialized vocabulary, with individuals with limited English proficiency.

We did not receive suggested revisions to the wording of this definition. Comments we received on the specific types of language assistance services mentioned in the definition are addressed in the relevant portions of the preamble to § 92.4 for those respective terms.

For clarity and consistency within the final rule, we are replacing several phrases in this definition with other terms to conform to changes made in other provisions of the final rule. First, in paragraph (1) regarding oral language assistance, we are adding the words “for an individual with limited English proficiency” after “qualified interpreter” because § 92.4 now defines “qualified interpreter for an individual with limited English proficiency” separately from a “qualified interpreter for an individual with a disability.” Also, because § 92.4 defines “qualified bilingual/multilingual staff,” we are replacing “bilingual or multilingual staff competent to communicate, in non-English languages using any necessary specialized vocabulary” with “the use of qualified bilingual/multilingual staff to communicate.” In paragraph (2) regarding written translation, we are replacing the reference to written translation of “documents and Web sites” to “written content in paper or electronic form.” Finally, because § 92.4 defines “qualified translator,” we are adding “performed by a qualified translator” after “written translation.”

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with technical revisions, as described in the preceding paragraph, to ensure consistency with other provisions of the final rule.

without the preceding descriptor of “written” refers to the communication of information in writing. See, e.g., U.S. Dep’t of Justice, Commonly Asked Questions and Answers Regarding Limited English Proficient (LEP) Individuals, <http://www.lep.gov/faqs/faqs.html#OneQ11> (last visited Mar. 15, 2016) (differentiating between interpreters and translators in FAQ 11); Interpreters and Translators, U.S. Dep’t of Labor, Bureau of Labor Statistics, Occupational Outlook Handbook, 2014–15, <http://www.bls.gov/ooh/media-and-communication/interpreters-and-translators.htm> (explaining that interpreters convert information in a spoken language and translators convert information in written language).

⁴⁹ 68 FR 47311, 47313 (Aug. 8, 2003).

⁵⁰ We use the terms “oral interpretation” and “written translation” for clarity. The term “interpretation” used without the preceding descriptor of “oral” refers to the communication of information orally and the term “translation” used

National origin. The proposed rule did not define the term “national origin.”

Comment: A few commenters recommended defining “race, color, or national origin” to include “language” and “immigration status.” Commenters asserted that “language” should be included to capture the application of national origin discrimination to individuals with limited English proficiency. As to immigration status, some commenters requested clarification that immigrants, and particularly non-U.S. citizens, are protected from discrimination on the basis of race, color, national origin, sex, age, or disability under Section 1557 and this part.

Response: In response to comments, we are providing further clarification on the scope of “national origin”; we determine it unnecessary to define “race” or “color.” Thus, this final rule defines “national origin” consistent with the well-established definition of the term that the Equal Employment Opportunity Commission (EEOC) uses in its interpretation of Title VII of the Civil Rights Act of 1964.⁵¹ This definition clarifies that national origin includes not only an individual’s place of origin, but also his or her ancestor’s place of origin, which reflects our intent that individuals born in the United States but who have an ancestry outside the United States are protected. This definition also clarifies that national origin includes an individual’s manifestation of the physical, cultural, or linguistic characteristics of a national origin group.⁵²

⁵¹ 29 CFR 1606.1 (defining “national origin discrimination”).

⁵² In addition, courts have adopted this principle. See, e.g., *Bennun v. Rutgers State Univ.*, 941 F.2d 154, 173 (3d Cir. 1991), cert. denied, 502 U.S. 1066 (1992) (stating that an individual’s birth in a foreign country where another culture predominates, immersion in that country’s ways of life, and speaking the native language in one’s home, are sufficient to identify the individual as part of a national origin group); *Fragante v. City and County of Honolulu*, 888 F.2d 591, 595–96 (9th Cir. 1989), cert. denied, 494 U.S. 1081 (1990) (stating that accent and national origin are inextricably intertwined in many cases); *Gutierrez v. Mun. Court of Southeast Jud. Dist., Los Angeles Cnty.*, 838 F.2d 1031, 1039 (9th Cir. 1988 vac’d and rem., 490 U.S. 1016 (1989)) (stating that “[b]ecause language and accents are identifying characteristics, ‘rules which have a negative effect on bilinguals, individuals with accents, or non-English speakers, may be mere pretexts for intentional national origin discrimination’”). A member of a religious group states a cognizable national origin discrimination claim under Title VI and Section 1557 and this part when that discrimination is based on a religious group’s shared ancestry or its physical, cultural, and linguistic characteristics rather than its members’ religious practice. See Letter from Thomas Perez, Assistant Attorney Gen., Civil Rights Div., U.S. Dep’t of Justice to Russlynn Ali, Assistant Sec’y for Civil Rights, Office for Civil Rights, U.S.

By contrast, we decline to include the term “immigration status” in the definition of “national origin.” An individual’s national origin is not the same as her citizenship or immigration status, and neither Title VI nor Section 1557 explicitly protects individuals against discrimination on the basis of citizenship or immigration status. However, as under Title VI, Section 1557 and this part protect individuals present in the United States, whether lawfully or not, who are subject to discrimination based on race, color, national origin, sex, age, or disability. Moreover, OCR considers an immigrant or noncitizen to state a cognizable national origin discrimination claim under Title VI,⁵³ Section 1557, and this part when the claim alleges that a covered entity’s use of a facially neutral policy or practice related to citizenship or immigration status has a disparate impact on individuals of a particular national origin group.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term “national origin” in § 92.4 to include an individual’s manifestation of the physical, cultural, or linguistic characteristics of a national origin group as well as an individual’s or her ancestor’s place of origin.

On the basis of sex. We proposed that the term “on the basis of sex” includes, but is not limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity.

We noted that Section 1557 extends the grounds for discrimination found in the nondiscrimination laws cited in the statute (*i.e.*, race, color, national origin, sex, age, or disability) to certain health programs and activities. We noted that the HHS Title IX regulation explicitly includes discrimination on the basis of

Dep’t of Educ. Re: Title VI and Coverage of Religiously Identifiable Groups, at 2 (Sept. 8, 2010), https://www.justice.gov/sites/default/files/crt/legacy/2011/05/04/090810_AAG_Perez_Letter_to_Ed_OCR_Title%20VI_and_Religiously_Identifiable_Groups.pdf.

⁵³ See Voluntary Resolution Agreement between U.S. Dep’t of Health & Human Servs., Office for Civil Rights and Ariz. Health Care Cost Containment System & the Ariz. Dep’t of Econ. Sec., OCR Transaction Nos. 10–117078 & 10–117875 (2015), <http://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/Arizona/vra.pdf> [hereinafter HHS OCR VRA with AZ Agencies] (resolving cognizable complaints of national origin discrimination under Title VI following implementation of a State law requiring State employees, in the administration of public benefits programs, to report “discovered violations of federal immigration law” to U.S. Immigration and Customs Enforcement).

pregnancy as a form of discrimination on the basis of sex, and we proposed that the definition in this section mirror that regulation.⁵⁴

We noted that the proposed inclusion of sex stereotyping reflects the Supreme Court’s holding in *Price Waterhouse v. Hopkins*,⁵⁵ and that discrimination based on stereotypical notions of appropriate behavior, appearance or mannerisms for each gender constitutes sex discrimination.

We proposed that discrimination on the basis of sex further includes discrimination on the basis of gender identity. We noted that like other Federal agencies,⁵⁶ HHS has previously interpreted sex discrimination to include discrimination on the basis of gender identity.⁵⁷ We also noted that courts, including in the context of Section 1557, have recognized that sex discrimination includes discrimination based on gender identity.⁵⁸ Thus, we proposed to adopt formally this well-

⁵⁴ See 45 CFR 86.40(b) (prohibiting discrimination on the basis of “pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom”).

⁵⁵ 490 U.S. 228, 250–51 (1989).

⁵⁶ See 5 CFR 300.102(c), 300.103(c), 300.103(c), 315.806(d), 335.103(b)(1), 537.105(d), 900.603(e) (U.S. Office of Personnel Management regulations providing that discrimination on the basis of sex includes discrimination on the basis of gender identity); Directive 2014–02, U.S. Dep’t of Labor, Office of Fed. Contract Compliance Programs, § 5 (Aug. 19, 2014), http://www.dol.gov/ofccp/regs/compliance/directives/dir2014_02.html; Statement of Interest of the United States, *Jamal v. SAKS & Co.*, No. 4:14–CV–2782 (S.D. Tex. Jan. 26, 2015) <https://www.justice.gov/sites/default/files/crt/legacy/2015/02/27/jamalsoi.pdf>; Statement of Interest of the United States, *Tooley v. Van Buren Pub. Sch.*, No. 2:14–cv–13466–AC–DRG (E.D. Mich. Feb. 24, 2015) <https://www.justice.gov/sites/default/files/crt/legacy/2015/02/27/tooleysoi.pdf>; Memo from Eric Holder, Att’y Gen., to U.S. Att’y’s & Heads of Dep’t Components (Dec. 18, 2014), <https://www.justice.gov/opa/pr/attorney-general-holder-directs-department-include-gender-identity-under-sex-discrimination>; U.S. Dep’t of Educ., Questions and Answers on Title IX and Sexual Violence, p. B–2, <http://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf>; Macy, 2012 WL 1435995, at *11.

⁵⁷ See Letter from Leon Rodriguez, Director, U.S. Dep’t of Health & Human Servs., Office for Civil Rights, to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights (Jul. 12, 2012), <https://www.nachc.com/client/OCRLetterJuly2012.pdf>.

⁵⁸ See, e.g., *Rumble v. Fairview Heath Servs.*, Civ. No. 14–cv–2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (Section 1557) (order denying motion to dismiss); *Barnes v. City of Cincinnati*, 401 F.3d 729, 737 (6th Cir.), cert. denied, 546 U.S. 1003 (2005) (Title VII); *Smith v. City of Salem, Ohio*, 378 F.3d 566, 575 (6th Cir. 2004) (Title VII); *Schroer v. Billington*, 577 F.Supp.2d 293, 304 (D.D.C. 2008) (Title VII). But see *Johnston v. Univ. of Pittsburgh*, 97 F.Supp.3d 657, 671 (W.D. Pa. 2015) (appeal docketed, No. 1502922) (3d Cir. Apr. 24, 2015) (holding that an individual treated in accordance with sex assigned at birth has not been discriminated against on the basis of sex under Title IX).

accepted interpretation of discrimination “on the basis of sex.”

OCR stated that as a matter of policy, we also support banning discrimination in health programs and activities on the basis of sexual orientation. We noted that current law is mixed on whether existing Federal nondiscrimination laws prohibit discrimination on the basis of sexual orientation as a part of their prohibitions on sex discrimination. However, we further noted that a recent U.S. EEOC decision, *Baldwin v. Department of Transportation*,⁵⁹ concluded that Title VII’s prohibition of discrimination “on the basis of sex” includes sexual orientation discrimination because discrimination on the basis of sexual orientation necessarily involves sex-based considerations.

We proposed that the final rule reflect the current state of nondiscrimination law, and we sought comment on the best way of ensuring that this rule includes the most robust set of protections supported by the courts on an ongoing basis.

Comment: Several commenters commended OCR’s inclusion of discrimination not only on the basis of pregnancy, but also on the basis of pregnancy-related procedures or conditions in the definition of “on the basis of sex” and noted that such a position is consistent with existing civil rights statutes. Other commenters noted concern that the inclusion of the phrase “termination of pregnancy” in the definition of “on the basis of sex” will be interpreted as requiring the provision or coverage of, or referral for, pregnancy termination, and urged OCR to state explicitly that neither Section 1557 nor the regulation imposes such a requirement.

Response: The definition of “on the basis of sex” established by this rule is based upon existing regulation and previous Federal agencies’ and courts’ interpretations that discrimination on the basis of sex includes discrimination on the basis of pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom.

Additionally, the final rule balances an individual’s right to access health programs and activities free from discrimination with protections for religious beliefs and practices. As we explained in the preamble to the proposed rule and have reiterated here, this rule does not displace existing protections afforded by, for example,

Federal provider conscience laws and RFRA. Again, with respect to concerns about potential conflicts between provisions of the final rule and individuals’ or organizations’ sincerely held religious beliefs, we refer to the discussion at § 92.2 in this preamble. With respect to abortion, moreover, nothing in Section 1557 displaces the ACA provisions regarding abortion, including but not limited to the provision that no qualified health plan offered through a Marketplace may discriminate against an individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions;⁶⁰ provisions that state that nothing in the ACA shall be construed to require a qualified health plan to provide coverage of abortion as an essential health benefit;⁶¹ and the provision permitting States to prohibit abortion coverage in qualified health plans and restricting the use of Federal funding for abortion services.⁶²

Comment: A significant number of commenters commended our inclusion of gender identity and sex stereotyping in the definition of “on the basis of sex” and noted that the inclusion is consistent with a growing body of legal precedent. Some commenters suggested OCR add transgender status and gender expression in the definition of “on the basis of sex” in order to make explicit our intention to protect individuals on these bases, consistent with previous court and Federal agency interpretations.

Conversely, a few commenters opined that the inclusion of gender identity discrimination as a form of discrimination on the basis of sex was based on erroneous interpretations of Title IX legislative history because Congressional intent to ban sex discrimination was based only on the biological classifications of males and females, not gender identity. A few commenters thought that OCR’s reliance on previously adopted Federal agencies’ interpretations was weak and unpersuasive and that the reliance on cases arising under Federal civil rights laws other than Title IX was misplaced, further pointing to a few recent court decisions under Title IX that rejected claims that discrimination on the basis of sex includes discrimination on the basis of gender identity.

A few commenters also suggested that the inclusion of “gender identity” as a prohibited basis of discrimination on the basis of sex may infringe upon

individual patients’ constitutional right to privacy by requiring those patients to participate in sex-specific programs or activities with a “non-biological” male or female and additionally contravenes employees’ and faith-based organizations’ religious beliefs by forcing them to participate in services affirming gender identity in violation of their religious convictions.

Response: The definition of “on the basis of sex” established by this rule is based upon existing regulation and previous Federal agencies’ and courts’ interpretations that discrimination on the basis of sex includes discrimination on the basis of gender identity and sex stereotyping. While OCR appreciates the commenters’ request that we add transgender status and gender expression to the definition of “on the basis of sex,” we do not believe that it is necessary to add these terms to the definition. As previously stated, we encompass these bases in the definition of “gender identity”; thus, references to “gender identity” include “gender expression” and “transgender status.” Because the definition of “on the basis of sex” includes gender identity, further reference to transgender status or gender expression here is superfluous.

OCR also believes that its inclusion of gender identity is well grounded in the law and disagrees with those commenters who argued to the contrary. As the Supreme Court made clear in *Price Waterhouse v. Hopkins*, in prohibiting sex discrimination, Congress intended to strike at the entire spectrum of discrimination against men and women resulting from sex stereotypes.⁶³ Courts after *Price Waterhouse* interpret Title VII’s protections against discrimination on the basis of sex as encompassing not only “sex,” or biological differences between the sexes, but also “gender” and its manifestations.⁶⁴ In essence, *Price Waterhouse* thus rejects the reasoning, and vitiates the precedential value, of earlier Federal appellate court decisions that limited Title VII’s coverage of “sex” to the anatomical and biological characteristics of sex. Moreover, courts frequently look to case law interpreting other civil rights provisions, including Title VII, for guidance in interpreting Title IX.⁶⁵

OCR’s approach accords with well-accepted legal interpretations adopted by other Federal agencies and courts.

⁵⁹ 490 U.S. at 251 (citations omitted).

⁶⁴ See, e.g., *Smith v. City of Salem, Ohio*, 378 F.3d 566, 573–74 (6th Cir. 2004).

⁶⁵ See, e.g., *Wolfe v. Fayetteville, Ark. Sch. Dist.*, 648 F.3d 860, 864 n.4 (8th Cir. 2011); *Weinstock v. Columbia Univ.*, 224 F.3d 33, 42 n.1 (2d Cir. 2000), cert. denied, 540 U.S. 811 (2003).

⁵⁹ U.S. Equal Employment Opportunity Comm’n Appeal No. 0120133080, Agency No. 2012–24738–FAA–03 (July 15, 2015), <http://www.eeoc.gov/decisions/0120133080.txt>.

⁶⁰ 42 U.S.C. 18023(b)(4).

⁶¹ 42 U.S.C. 18023(b)(1)(A).

⁶² 42 U.S.C. 18023.

For example, Title IX Guidance issued by the U.S. Department of Education generally requires recipients of federal financial assistance to treat transgender students consistent with their gender identity.⁶⁶ The Fourth Circuit reversed a lower court decision dismissing the Title IX sex discrimination claim of a transgender student prohibited from using the school bathroom consistent with his gender identity, holding that the Department of Education's interpretation of its regulation was not plainly erroneous, and thus was entitled to controlling weight.⁶⁷

The fact that there may be circumstances in which it is permissible to make sex-based distinctions is not a license to exclude individuals from health programs and activities for which they are otherwise eligible simply because their gender identity does not align with other aspects of their sex, or with the sex assigned to them at birth. The Department has a responsibility to ensure that health programs and activities of covered entities are carried out free from such discrimination.

To the extent that privacy considerations may be relevant in an anti-discrimination analysis, OCR will consider these interests in the context of individual complaints. We note, however, that at least one court has rejected a claim that an individual's legal right to privacy is violated simply by permitting another person access to a sex-specific program or facility that corresponds to their gender identity.⁶⁸ With respect to concerns about potential conflicts between provisions of the final rule and individuals' or organizations' sincerely held religious beliefs, we refer to the discussion at § 92.2 in this preamble.

Comment: A few commenters recommended that OCR clarify that the prohibition on sex discrimination extends to discrimination on the basis of the presence of atypical sex characteristics and intersex traits (*i.e.*, people born with variations in sex

characteristics, including in chromosomal, reproductive, or anatomical sex characteristics that do not fit the typical characteristics of binary females or males). At least one commenter noted that this clarification is necessary because intersex people may face discrimination when medical providers or insurance companies follow policies which deem certain medical procedures available to only one sex, thereby excluding intersex people who may be registered under another sex.

Response: We agree with the commenters that the prohibition on sex discrimination extends to discrimination on the basis of intersex traits or atypical sex characteristics. OCR intends to apply its definition of "on the basis of sex" to discrimination on these bases.

Comment: Many commenters requested that OCR explicitly state in the rule that Section 1557's prohibition of discrimination on the basis of sex includes discrimination on the basis of sexual orientation. Other commenters asserted that Section 1557 did not intend to protect against sexual orientation discrimination and that OCR does not have authority to include this basis because no Federal appellate court has interpreted Title IX's or Title VII's ban on sex discrimination to protect same-sex relationships or conduct.

Response: As we noted in the preamble to the proposed rule, we support a prohibition on discrimination based on sexual orientation as a matter of policy. We believe that it is critical to meeting the goals of Section 1557 and, more broadly, the ACA, to ensure equal access to health care and health coverage. Indeed, these policy goals are reflected in the increasing number of actions taken by Federal agencies to ensure that lesbian, gay, and bisexual individuals are protected from discrimination. For example, CMS regulations bar discrimination on the basis of sexual orientation by Health Insurance Marketplaces and issuers offering qualified health plans;⁶⁹ Medicare regulations prohibit the restriction of visitation rights in hospitals based on sexual orientation (or gender identity);⁷⁰ and the Social Security Administration is now processing Medicare enrollments for same-sex spouses.⁷¹ Court decisions have, moreover, repeatedly made clear that individuals and couples deserve

equal rights regardless of their sexual orientation.⁷²

The preamble to the proposed rule stated our policy position and noted that "[t]he final rule should reflect the current state of nondiscrimination law, including with respect to prohibited bases of discrimination" while seeking comment on the issue. While the preamble observed that no Federal appellate court has concluded to date "that Title IX's prohibition of discrimination 'on the basis of sex'—or Federal laws prohibiting sex discrimination more generally—prohibits sexual orientation discrimination," it also noted recent court decisions that have prohibited discrimination in cases involving allegations of discrimination relating to an individual's sexual orientation on the grounds that such discrimination is discrimination on the basis of sex stereotyping.

*Price Waterhouse v. Hopkins*⁷³ is the foundational decision that underlies these legal developments. Though *Price Waterhouse* did not involve an allegation of discrimination based on an individual's sexual orientation, the Supreme Court recognized in that case that unlawful sex discrimination occurs where an individual is treated differently based on his or her failure to conform to gender-based stereotypes about how men or women should present themselves or behave. The Department of Justice has therefore taken the position that a well-pled complaint alleging discrimination against a gay employee because of his failure to conform to sex stereotypes states a viable sex discrimination claim under Title VII.⁷⁴ When a covered entity discriminates against an individual based on his or her sexual orientation, the entity may well rely on stereotypical notions or expectations of how members of a certain sex should act or behave. These stereotypes are precisely the type of gender-based assumptions prohibited by *Price Waterhouse*.⁷⁵

⁶⁶ U.S. Dep't of Education, Office for Civil Rights, Questions and Answers in Title IX and Single Sex Elementary and Secondary Classes and Extra-Curricular Activities, (2014), <http://www2.ed.gov/about/offices/list/ocr/docs/faqs-title-ix-single-sex-201412.pdf>.

⁶⁷ *G. ex rel. Grimm v. Gloucester Cty. Sch. Bd.*, No. 15–2056, 2016 WL 1567467 at * 6 (4th Cir. 2016).

⁶⁸ See *e.g.*, *Crosby v. Reynolds*, 763 F. Supp. 666 (D. Me. 1991) (requiring female prisoner to share a cell with a transgender woman violated no clearly established constitutional right); *cf. Cruzan v. Special Sch. Dist., #1*, 294 F.3d 981 (8th Cir. 2002) (per curiam) (teacher's assertion that her personal privacy was invaded when school permitted a transgender woman to use women's restroom was not cognizable under employment discrimination law).

⁶⁹ 45 CFR 155.120(c)(1)(ii); 156.200(e).

⁷⁰ 42 CFR 482.13(h)(3).

⁷¹ <http://www.medicare.gov/sign-up-change-plans/same-sex-marriage.html> (last visited Mar. 11, 2016).

⁷² For example, in 1996, the Supreme Court struck down an amendment to the Colorado constitution that prohibited the State government from providing any legal protections to gay, lesbian, and bisexual individuals. *Romer v. Evans*, 517 U.S. 620 (1996). And, just last year, the Supreme Court ruled in *Obergefell v. Hodges*, 135 S. Ct. 2584 (2015), that states may not prohibit same-sex couples from marrying and must recognize the validity of same-sex couples' marriages.

⁷³ 490 U.S. 228 (1989).

⁷⁴ See Def.'s Renewed Mot. to Dismiss at 18–19, *Terveer v. Billington*, No. 1:12–cv–1290, ECF No. 27 (D.D.C. Mar. 21, 2013).

⁷⁵ See, *e.g.*, *Deneffe v. SkyWest, Inc.*, No. 14–cv–00348, 2015 WL 2265373, at * (D. Colo. May 11, 2015); *Terveer v. Billington*, 34 F. Supp. 3d 100, 116 (D.D.C. 2014); *Boutillier v. Hartford Pub. Schs.*,
Continued

Based on this understanding, some courts have recognized in the wake of *Price Waterhouse* that discrimination “because of sex” includes discrimination based on sex stereotypes about sexual attraction and sexual behavior⁷⁶ or about deviations from “heterosexually defined gender norms.”⁷⁷ For example, a recent district court decision in the Ninth Circuit held that the distinction between discrimination based on gender stereotyping and discrimination based on sexual orientation is artificial, and claims based on sexual orientation are covered by Title VII and Title IX, not as an independent category of claims separate from sex and gender stereotyping, but as sex or gender discrimination.⁷⁸

In addition, in *Baldwin v. Department of Transportation* the EEOC concluded that Title VII’s prohibition of discrimination “because of sex” includes sexual orientation discrimination because discrimination on the basis of sexual orientation necessarily involves sex-based considerations.⁷⁹ The EEOC relied on several theories to reach this conclusion: A plain reading of the term “sex” in the statutory language, an associational theory of discrimination based on “sex,” and the gender stereotype theory announced in *Price Waterhouse*.

For all of these reasons, OCR concludes that Section 1557’s prohibition of discrimination on the basis of sex includes, at a minimum, sex discrimination related to an individual’s sexual orientation where the evidence establishes that the discrimination is based on gender stereotypes. Accordingly, OCR will evaluate complaints alleging sex discrimination related to an individual’s sexual

orientation to determine whether they can be addressed under Section 1557.

OCR has decided not to resolve in this rule whether discrimination on the basis of an individual’s sexual orientation status alone is a form of sex discrimination under Section 1557. We anticipate that the law will continue to evolve on this issue, and we will continue to monitor legal developments in this area. We will enforce Section 1557 in light of those developments and will consider issuing further guidance on this subject as appropriate.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 without modification.

Qualified bilingual/multilingual staff. In the proposed rule, we proposed to define “language assistance services” to include, as a type of oral language assistance, the use of staff members who are “competent to communicate, in non-English languages using any necessary specialized vocabulary, directly with individuals with limited English proficiency.”⁸⁰ The proposed rule did not define the term “qualified bilingual/multilingual staff.”

Comment: Some commenters observed that as an alternative to providing oral interpretation, many covered entities rely on staff members to serve individuals with limited English proficiency in their respective primary languages. According to these commenters, covered entities mistakenly assume that staff members who possess a rudimentary familiarity with at least one non-English language are competent to provide oral language assistance for the covered entity’s health program or activity. Commenters asked us to require covered entities to assess the proficiency of staff members who communicate directly with individuals with limited English proficiency in their respective primary languages.

Response: In response to commenters’ observations, we have defined the term “qualified bilingual/multilingual staff” in § 92.4 to clarify the knowledge, skills, and abilities that a staff member must demonstrate for a covered entity to designate that staff member to provide effective oral language assistance.⁸¹ Specifically, qualified bilingual/multilingual staff must demonstrate to

the covered entity that they are proficient in English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and are able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary language. An individual who meets the definition of “qualified bilingual/multilingual staff” does not necessarily qualify to interpret or translate for individuals with limited English proficiency within the meaning of this rule.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term “qualified bilingual/multilingual staff” in § 92.4 to clarify that such an individual must be proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and must be able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.

Qualified interpreter. We proposed that the term “qualified interpreter” means an individual who has the characteristics and skills necessary to interpret for an individual with a disability, for an individual with limited English proficiency, or for both. In the proposed rule, the language in paragraph (1), applicable for interpreting for an individual with a disability, is the same as language in the regulations implementing Titles II and III of the ADA, at 28 CFR 35.104 and 36.104, respectively. The language in paragraph (2) of the proposed rule, applicable for interpreting for an individual with limited English proficiency, reflects a synthesis of the attributes, described in the Department’s LEP Guidance, that are necessary for an individual to interpret competently and effectively under the circumstances and thus to provide the effective oral language assistance services required under the law.⁸² We noted that the fact

2014 WL 4794527 at *2 (D. Conn. 2014); *Koren v. The Ohio Bell Tel. Co.*, 894 F. Supp.2d 1032, 1037–38 (N.D. Ohio. 2012); *Heller v. Columbia Edgewater Country Club*, 195 F. Supp.2d 1212, 1224, *adopted*, 195 F. Supp.2d 1216 (D. Or. 2002); *Centola v. Potter*, 183 F. Supp.2d 403, 410 (D. Mass. 2002).

⁷⁶ See *Videckis and White v. Pepperdine Univ.*, No. 15–00298, 2015 WL 8916764 (C.D. Cal. Dec. 15, 2015) (denying motion to dismiss).

⁷⁷ *Isaacs v. Felder*, No. 2:13 cv 693, 2015 WL 6560655, at * 9 (M.D. Ala. Oct. 29, 2015) (internal quotation marks omitted).

⁷⁸ *Videckis*, 2015 WL 8916764. Prior circuit court decisions have drawn such distinctions. See, e.g., *Dawson v. Bumble & Bumble*, 398 F.3d 211, 218 (2d Cir. 2005); *Vickers v. Fairfield Med. Ctr.*, 453 F.3d 757, 763 (6th Cir. 2006).

⁷⁹ U.S. Equal Employment Opportunity Comm’n Appeal No. 0120133080, Agency No. 2012–24738–FAA–03 (July 15, 2015), <http://www.eeoc.gov/decisions/0120133080.txt> (finding that sexual orientation is inseparable from and inescapably linked to sex and thus that an allegation of discrimination based on sexual orientation is necessarily an allegation of sex discrimination).

⁸⁰ See 80 FR at 54176, 54216.

⁸¹ See HHS LEP Guidance, *supra* note 49, 68 FR at 47317 (stating that the covered entity may provide oral language assistance through bilingual staff members that are “competent to communicate directly with [limited English proficient] persons in their language”).

⁸² See HHS LEP Guidance, 68 FR at 47311, 47316 (explaining that an individual’s proficiency in another language, knowledge of specialized terminology, and adherence to interpreter ethics are considerations in determining competency to interpret); *id.* at 47317–18, 47323 (discussing why family members, friends, and ad hoc interpreters may not be competent to interpret); The language is also consistent with the approach we have taken in our Title VI enforcement efforts. See, e.g., Voluntary Resolution Agreement between U.S. Dep’t of Health & Human Servs., Office for Civil Rights and Mee Memorial Hosp., OCR Transaction

that an individual has above average familiarity with speaking or understanding a language other than English does not suffice to make that individual a qualified interpreter for an individual with limited English proficiency.

We proposed that the definition of “qualified interpreter” includes criteria regarding interpreter ethics, including maintaining client confidentiality. As we stated in the proposed rule, bilingual or multilingual staff members may not possess competence in the skill of interpreting nor have knowledge of generally accepted principles of interpreter ethics. A qualified bilingual/multilingual nurse who is competent to communicate in Spanish directly with Spanish-speaking individuals may not be a qualified interpreter for an individual with limited English proficiency if serving as an interpreter would pose a conflict of interest with the nurse’s treatment of the patient.

Comment: A few commenters suggested that OCR amend the definition of qualified interpreter to require interpreters to be licensed by State law in the State where the entity is providing services. Other commenters suggested that OCR require interpreters to be certified by a national nonprofit certification organization.

Response: We recognize the commenters’ concerns regarding licensure and certification, but we decline to accept these recommendations. Although OCR considers licensure and certification as evidence that an interpreter is qualified, licensure and certification are neither necessary nor sufficient evidence of qualification for the following reasons.⁸³ First, OCR does not wish to unduly narrow the pool of qualified interpreters available to a covered entity by requiring certification or licensure; many interpreters who are currently unlicensed and uncertified are competent to translate at a level that

would meet the requirements of Section 1557 and this part.

Second, there are several organizations, both for-profit and non-profit, that offer certification programs for interpreters. Even if the credentialing standards developed by those organizations currently satisfy Section 1557 requirements, the organizations’ standards are subject to change and there is no assurance that such standards would consistently meet the standards of Section 1557. In addition, other national credentialing organizations could be established whose standards failed to meet the requirements of the law. Similar issues with respect to new and changing standards could also arise in the State licensing context.

Third, there are factors unrelated to credentials that could cause OCR to determine that an interpreter is unqualified. For example, if an interpreter has not practiced in a long time or is late to appointments, the interpreter might be unqualified regardless of the interpreter’s State or non-profit credentials. For all of these reasons, we decline to amend the definition of qualified interpreter in the ways these commenters proposed.

Comment: We received many comments in support of the proposed rule’s inclusion of a definition of “qualified interpreter.” Some commenters, however, requested that we define a qualified interpreter who interprets for individuals with limited English proficiency separately from a qualified interpreter who interprets for individuals with disabilities, noting that there are significant differences between the provision of oral interpretation services in these two contexts. Other commenters suggested broadening the lexicon an interpreter must possess to be a qualified interpreter for a particular covered entity’s health program. Specifically, commenters suggested that an interpreter’s required knowledge and abilities to be “qualified” should include not only knowledge of any necessary specialized vocabulary but also knowledge of terminology and phraseology.

Response: We have modified § 92.4 to provide separate definitions of “qualified interpreter for an individual with limited English proficiency”⁸⁴ and

“qualified interpreter for an individual with a disability.” We agree that it is important to account for the qualifications necessary for interpreting for each set of individuals. In addition, we added the words “terminology” and “phraseology” in both definitions to align the final rule’s description of the requisite knowledge, skills, and abilities an interpreter must possess with those recognized within the field.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we no longer define “qualified interpreter” as one term. We are using the content from proposed paragraphs (1), (1)(i), and (2) to create a separate definition for “qualified interpreter for an individual with a disability” and similarly use the content from proposed paragraphs (1) and (1)(ii) to create a separate definition for “qualified interpreter for an individual with limited English proficiency.” For both definitions, we added “terminology and phraseology” to the lexicon a qualified interpreter in both contexts must possess.

Qualified translator. The proposed rule did not use or define the term “qualified translator.”

Comment: We received a significant number of comments recommending that the proposed rule define “qualified translator.” Commenters explained that bilingual individuals do not necessarily possess the skill of translating or the knowledge of specialized terminology to be able to translate written documents from English to another language. Similarly, a qualified interpreter for an individual with limited English proficiency may not possess the knowledge, skills, and abilities to translate, as the skill of interpreting is different from the skill of translating.⁸⁵

Response: In response to commenters’ recommendations, we are adding the term “qualified translator” to the final rule. The final rule defines qualified translator as someone who translates effectively, accurately, and impartially; adheres to generally accepted translator ethics principles; and is proficient in both written English and at least one other written non-English language, including any necessary specialized vocabulary, terminology and phraseology. We agree with commenters that even if an individual meets the definition of “qualified bilingual/multilingual staff” or “qualified interpreter for an individual with

Nos. 12–143846, 13–1551016 & 13–153378, pt. II.J. (2014) [hereinafter HHS OCR VRA with Mee Memorial Hospital], <http://www.hhs.gov/ocr/civilrights/activities/agreements/mee.html> (defining qualified interpreter); Voluntary Resolution Agreement between U.S. Dep’t of Health & Human Servs., Office for Civil Rights and Montgomery County Dep’t of Soc. Servs., OCR Transaction No. 08–79992, pts. II.E (defining qualifications of an “interpreter” under the agreement), IV.H (requiring timely, competent language assistance); & IV.L (identifying interpreter standards) [hereinafter HHS OCR VRA with Montgomery County DSS], <http://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/examples/limited-english-proficiency/MCDSS-resolution-agreement/index.html>.

⁸³ See HHS LEP Guidance, 68 FR at 47316 (“Competency to interpret, however, does not necessarily mean formal certification as an interpreter, although certification is helpful.”).

⁸⁴ We note that this final rule uses the terms “qualified interpreter for an individual with limited English proficiency” interchangeably with “qualified interpreter for the individual with limited English proficiency” and “qualified interpreter to an individual with limited English proficiency.” The preposition and article used within the phrase do not represent a change in meaning.

⁸⁵ See HHS LEP Guidance, *supra* note 49, 68 FR at 47316; Int’l Medical Interpreters Assoc., Guide on Medical Translation 4 (Jan. 2009), <http://www.imiaweb.org/uploads/pages/438.pdf>.

limited English proficiency” under this rule, that individual does not necessarily possess the knowledge, skills, or abilities to translate written content in paper or electronic form used in a covered entity’s health programs or activities.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term “qualified translator” in § 92.4 to set out the competencies an individual must have to translate written content in paper or electronic form in the covered entity’s health programs or activities.

Sex stereotypes. We proposed that the term “sex stereotypes” refers to stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. We noted that these stereotypes can include expectations that gender can only be constructed within two distinct opposite and disconnected forms (masculinity and femininity), and that gender cannot be constructed outside of this gender construct.

Comment: Commenters suggested that OCR revise the definition of “sex stereotypes” because, while accurate in describing the types of assumptions that may motivate discrimination against non-binary individuals, the definition is cumbersome and may not be readily understood by persons not familiar with the issue. Several commenters expressed concern that the proposed language might be interpreted as limiting sex discrimination based on sex stereotyping to only include discrimination based on gender identity. Commenters suggested affirming in the final rule that any form of sex discrimination on the basis of sex stereotypes constitutes sex discrimination, whether or not it also constitutes discrimination on the basis of gender identity. Some commenters requested that OCR provide examples illustrating discrimination based on sex stereotypes that can form the basis of prohibited sex discrimination.

Several commenters suggested that OCR clarify the definition of “sex stereotypes” to address the relationship between sex stereotypes and sexual orientation. In this regard, commenters suggested that OCR revise the definition of “sex stereotypes” to add that “sex-stereotypes also include gendered expectations related to the appropriate roles of men and women, such as the expectation that women are primary

caregivers, and aspects of an individual’s sexual orientation, such as the sex of an individual’s sexual or romantic partners.”

Response: We have added a reference in the regulatory text to make clear that sex stereotypes include gendered expectations related to the appropriate roles of a certain sex.⁸⁶ With regard to sexual orientation, we refer commenters to the discussion in the preamble addressing the definition of “on the basis of sex.”⁸⁷

Comment: Some commenters stated that the proposed definition of sex stereotypes is unprecedented in its breadth with no legal authority to support the proposition that individuals who claim to identify with non-binary genders constitute a protected class under Title IX or any other Federal law. Commenters suggested that it is impossible for an individual to have a non-binary gender identity.

Response: OCR has adopted the approach taken by the Federal government and numerous courts in similar matters—that sex stereotypes encompass not only stereotypes concerning the biological differences between the sexes, but also include stereotypes concerning gender norms.⁸⁸ As stated in the preamble to the proposed rule and clarified in the final rule, OCR recognizes that sex stereotypes can include the expectation that individuals consistently identify with only one of two genders (male or female), and that they act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes can also include a belief that gender can only be binary and thus that individuals cannot have a gender identity other than male or female. OCR recognizes that an individual’s gender identity involves the interrelationship between an individual’s biology, gender, internal sense of self and gender expression related to that perception; thus, the gender identity spectrum includes an array of possible gender identities beyond male and female.

⁸⁶ See, e.g., *Chadwick v. Wellpoint, Inc.*, 561 F.3d 38, 45 (1st Cir. 2009) (adverse employment action based on assumption that women are responsible for family caregiving and will perform their jobs less well as a result of caregiving responsibilities is discrimination based on sexual stereotypes in violation of Title VII). See also *Glenn v. Brumby*, 663 F.3d 1312 (11th Cir. 2011) (“These instances of discrimination against plaintiffs because they fail to act according to socially prescribed gender roles constitute discrimination under Title VII according to the rationale of *Price Waterhouse*.”).

⁸⁷ See discussion § 92.4, *supra*.

⁸⁸ See *Price Waterhouse*, 490 U.S. at 251; *Smith*, 378 F.3d. at 573 (citations omitted).

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with the following modifications: We have clarified that sex stereotypes can be based on expectations about gender roles.

Taglines. In the proposed rule, we defined taglines as short statements written in non-English languages to alert individuals with limited English proficiency to the availability of language assistance services, free of charge, and how the services can be obtained.⁸⁹ We did not receive comments with suggested revisions to the wording of this definition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 without modification.

Assurances Required (§ 92.5)

In § 92.5, we proposed that each entity applying for Federal financial assistance, each issuer seeking certification to participate in a Health Insurance MarketplaceSM, and each state seeking approval to operate a State-based MarketplaceSM be required to submit an assurance that its health programs and activities will be operated in compliance with Section 1557. We noted that the regulations implementing Title VI, Title IX, Section 504, and the Age Act all require similar assurances. We modeled the assurance, duration of obligation, and covenants language on the Section 504 regulation.⁹⁰ We also proposed to revise the Assurance of Compliance HHS–690 Form to include all civil rights laws, including Section 1557, with which covered entities must comply.

The comments and our responses regarding § 92.5 are set forth below.

Comment: Several commenters recommended that OCR require covered entities to collect data on race, ethnicity, language, sex, gender, gender identity, sexual orientation, disability, and age. These commenters suggested that covered entities should be required to assess the populations they serve so that the covered entities can better plan how to meet the needs of those populations.

⁸⁹ The HHS LEP Guidance, *supra* note 49, 68 FR at 47320, describes the practice of tagging non-English statements on the front of common documents, such as “brochures, booklets, and in outreach and recruitment information” informing individuals with limited English proficiency of the availability of language assistance services.

⁹⁰ 45 CFR 84.5.

The commenters also urged that OCR require annual submission of the data to OCR and develop standards to address training on data collection, privacy protections, safeguarding, voluntary reporting by patients, and supporting analyses based on multiple variables.

Response: OCR agrees that data collection is an important tool that can help covered entities to better serve their communities, and encourages covered entities to regularly evaluate the impact of the services they provide on different populations. However, OCR declines to require data collection as part of the assurances required under Section 1557. The Department collects data pursuant to Section 4302 of the ACA, and OCR has access to these data. In addition, OCR has the authority to require covered entities to collect data and to provide OCR access to information under §§ 92.302 and 92.303 of this part,⁹¹ and will exercise this authority as needed and appropriate under particular circumstances in the future. With respect to recipients and State-based Marketplaces, §§ 92.302(a) and 92.302(b) incorporate the procedural provisions in the Title VI and the Age Act implementing regulations regarding enforcement actions under this part. Pursuant to these procedural provisions, when a recipient or State-based MarketplaceSM fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may find noncompliance with Section 1557 and initiate appropriate enforcement procedures, including beginning the process for fund suspension or termination and taking other action authorized by law. OCR has inserted a new subsection (c) to § 92.302 to clarify that it has that authority, and the text that was previously found at § 92.302(c) has been moved to the new § 92.302(d).

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.5 without modification.

⁹¹ Section 92.302 incorporates provisions of the Title VI implementing regulation with respect to enforcement actions concerning discrimination on the basis of race, color, national origin, sex, age, or disability. Those provisions authorize OCR to collect reports from recipients as necessary to determine compliance. Section 92.303 incorporates provisions in the Section 504 implementing regulation with respect to discrimination on the basis of prohibited criteria in health programs or activities administered by the Department. Those provisions authorize OCR to initiate actions as necessary to ensure compliance.

Remedial Action and Voluntary Action (§ 92.6)

In § 92.6, we proposed provisions addressing remedial action and voluntary action by covered entities. In paragraph (a), we proposed that a recipient or State-based MarketplaceSM that has been found to have discriminated on any of the bases prohibited by Section 1557 be required to take remedial action as required by the Director to overcome the effects of that discrimination. We proposed that similar to recipients and State-based Marketplaces, the Department, including the Federally-facilitated Marketplaces, is also obligated to address discrimination, but is subject to a different remedial process than recipients and State-based Marketplaces. In paragraph (b), we proposed to permit but not require all covered entities to take voluntary action in the absence of a finding of discrimination to overcome the effects of conditions that result or resulted in limited participation by persons based on race, color, national origin, sex, age, or disability. The provisions at §§ 92.6(a) and (b) are modeled after the Title VI, Title IX, Section 504, and Age Act regulations.

The comments and our responses regarding § 92.6 are set forth below.

Comment: One commenter requested that OCR specifically list the remedial actions available to OCR as well as the circumstances under which such remedial actions will be taken.

Response: In the discussion of enforcement mechanisms and procedures in the preamble to the proposed rule, OCR identified the range of enforcement tools available to OCR. However, it would not be feasible to specify the circumstances in which specific remedial actions would be taken. OCR evaluates each situation on a case-by-case basis and may use different remedial actions in different cases. In all cases, OCR attempts to achieve compliance and, in our experience, this approach has been successful.

Comment: One commenter requested clarification of the word “control” in the part of the regulation that states that where a recipient exercises “control” over a recipient that has discriminated, the Director may require both entities to take remedial action. Another commenter suggested that OCR only pursue remedial action against the entity actually found to have discriminated against an individual and not against the controlling entity.

Response: OCR declines to further define the word “control” as used in the

regulation. This term has appeared in civil rights regulations enforced by OCR for many years, and its meaning has been established over time. OCR also declines to limit its authority to pursue remedial action with respect to an entity that exercises control over an entity that has discriminated. This too is longstanding authority under OCR’s other authorities, and in OCR’s experience, controlling entities that are recipients often play an important role in securing appropriate action to remedy discrimination.

Comment: One commenter suggested that there be limitations on the uses of remedial action. Specifically, the commenter stated that OCR should require remedial action only on behalf of individuals who either (1) applied to participate but were unable to participate due to alleged discrimination; or (2) had been participants and were subject to alleged discrimination. The commenter asserted that without such limitations, covered entities could be unfairly exposed to claims by individuals who would not have been participants notwithstanding any alleged discrimination.

Response: OCR does not believe that limiting the availability of remedial action as suggested is appropriate. It would not be consistent with Section 1557’s and OCR’s commitment to eliminating discrimination in all parts of a program or activity and remedying discrimination, where necessary, with respect to harmed individuals.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.6 without modification.

Designation of Responsible Employee and Adoption of Grievance Procedures (§ 92.7)

In § 92.7, we proposed requirements for each covered entity that employs 15 or more persons to designate a responsible employee to coordinate the entity’s compliance with the rule and adopt a grievance procedure. Many entities covered by Section 1557 and this part are already required to designate a compliance coordinator and have a written process in place for handling grievances with respect to disability discrimination in all programs and activities or sex discrimination in education programs or activities.⁹²

⁹² Under Section 504, a recipient of Federal financial assistance with 15 or more employees must designate at least one individual to coordinate the covered entity’s compliance with Section 504’s

Continued

In paragraph (a), we proposed that a covered entity that employs 15 or more persons be required to designate at least one employee to coordinate compliance with the requirements of the rule. We noted that a covered entity that has already designated a responsible employee pursuant to the regulations implementing Section 504 or Title IX may use that individual to coordinate its efforts to comply with Section 1557.

In paragraph (b), we proposed that a covered entity that employs 15 or more persons be required to adopt a grievance procedure that incorporates appropriate due process standards and allows for the prompt and equitable resolution of complaints concerning actions prohibited by Section 1557 and this part. We noted that a covered entity that already has a grievance procedure addressing claims of disability discrimination that meets the standards established under the Section 504 regulation may use that procedure to address disability claims under Section 1557. In addition, we noted that covered entities may use that procedure to address all other Section 1557 claims, provided that the entity modifies the procedure to apply to race, color, national origin, sex, and age discrimination claims.

We proposed that for the Department, including Federally-facilitated Marketplaces, OCR will be deemed the responsible employee. In addition, we proposed that OCR's procedures for addressing complaints of discrimination on the grounds protected under Section 1557 will be deemed grievance procedures for the Department, including for the Federally-facilitated Marketplaces.

In the proposed rule, OCR invited comment on whether all covered entities, not only those that employ 15 or more persons, should be required to designate responsible employees and establish grievance procedures.

The comments and our responses regarding § 92.7 are set forth below.

Comment: Some commenters opposed inclusion of proposed § 92.7, arguing that it is unnecessary and costly and has few benefits because discrimination in

health programs and activities does not exist. Other commenters urged that Federal regulation in this area constrains covered entities' flexibility to decide how to address individuals' complaints of discrimination. Specifically, these commenters encouraged OCR to allow covered entities to retain existing internal grievance processes, leverage grievance processes within State agencies or within other entities, or develop new grievance procedures.

Response: We recognize commenters' concerns, but we disagree with commenters regarding the necessity of proposed § 92.7. To promote the effective and efficient implementation of Section 1557 and this part, it is necessary for covered entities with 15 or more employees to identify at least one individual accountable for coordinating the covered entity's compliance and to have a written process in place for handling grievances. We recognize that not all covered entities are organized and operate in the same way. Thus, we do not prescribe who in the covered entity must serve as the responsible employee—nor do we prohibit combining this function with other duties so long as there is no conflict of interest.

In addition, we disagree with commenters that proposed § 92.7 is costly, limits covered entities' flexibility, or conflicts with existing internal or State-mandated grievance procedures. As we stated in the proposed rule, recipients of Federal financial assistance with 15 or more employees, as well as the State-based Marketplaces, could increase the responsibilities of an already-designated coordinator to include the coordination of compliance with Section 1557 and this part.⁹³ These entities could also increase the scope of the existing grievance procedures required under Section 504 and the ADA to accommodate complaints of discrimination addressing all bases prohibited under Section 1557. Moreover, nothing in the rule bars a covered entity from combining the grievance procedure required under Section 1557 with procedures it uses to address other grievances, including those unrelated to individuals' civil rights. As described in the Regulatory Impact Analysis of the proposed rule⁹⁴ and reiterated in the Regulatory Impact Analysis to this final rule, the costs associated with these requirements are estimated to be minimal.

Comment: Some commenters stated that the final rule should specify minimum regulatory requirements for the grievance procedure required in § 92.7(b). Such minimum requirements would include, for instance: Timeframes for filing, resolving, and issuing written decisions regarding complaints; an appeal process; notice regarding retaliation protections; and clarification that no person needs to exhaust a covered entity's grievance procedure prior to filing a Section 1557 complaint with OCR. These commenters urged OCR to adopt regulatory requirements, instead of a model grievance procedure only, stating that a model policy alone is insufficient to ensure that an entity's grievance procedure provides meaningful rights and protections.

Response: We understand the commenters' concerns, but we decline to promulgate minimum standards for the content of the grievance procedure required in § 92.7(b); such an approach would be too prescriptive. Because Section 1557 and this part cover a variety of types of entities, we want to preserve flexibility for entities to adapt the rule's requirements to their own health programs and operational capacity, so long as the rules result in the prompt and equitable resolution of complaints. However, to provide covered entities an example of how to structure a grievance procedure that affords individuals appropriate procedural safeguards and provides for the prompt and equitable resolution of complaints, we have included a sample procedure as Appendix C. We disagree with commenters that a sample grievance procedure is insufficient; rather, a sample grievance procedure provides guidance to covered entities while also preserving their flexibility. In response to commenters' suggestion that we note that an individual need not exhaust a covered entity's grievance procedure prior to filing a Section 1557 complaint, we clarify that no such exhaustion requirement exists, as reflected in the sample grievance procedure included as Appendix C to the final rule.

Comment: Many commenters supported the alternate approach that would require covered entities with fewer than 15 employees to comply with § 92.7. These commenters reasoned that requiring all covered entities to designate a coordinator and establish a grievance procedure would give each entity the internal mechanisms to resolve compliance issues earlier and informally, allowing them to potentially avoid a formal investigation by OCR. Accordingly, these commenters asserted that the importance of extending

prohibition of disability discrimination and must have a written process in place for handling grievances. 45 CFR 84.7(a). Under Title IX, a recipient of Federal financial assistance must designate at least one individual to coordinate the recipient's compliance with Title IX's prohibition of sex discrimination with respect to the recipient's education program or activity and must have a written process in place for handling grievances. 45 CFR 86.8(a). Under Title II of the ADA, an entity with 50 or more employees must designate at least one individual to coordinate the covered entity's compliance with Title II's prohibition of disability discrimination and must have a written process in place for handling grievances. 28 CFR 35.107(a).

⁹³ See 80 FR 54172, 54202 (Sept. 8, 2015).

⁹⁴ *Id.*

required compliance with § 92.7 to covered entities with fewer than 15 employees justified the anticipated additional expense of compliance.

Some commenters observed that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule already requires many entities covered by Section 1557 and this part to implement grievance policies and identify compliance coordinators, regardless of the number of employees of the entity.⁹⁵ The commenters suggested that the implementation of these requirements under the HIPAA Privacy Rule has given entities with fewer than 15 employees covered by both the HIPAA Privacy Rule and Section 1557 and this part the experience necessary to implement the similar requirements of § 92.7. Because many of the covered entities with fewer than 15 employees, such as most health care providers receiving Federal financial assistance, are subject to the HIPAA Privacy Rule, commenters asserted that extending the requirements of § 92.7 to covered entities with fewer than 15 employees would impose a limited burden.

Conversely, some commenters suggested that compliance with § 92.7 would be too time consuming and costly for covered entities with fewer than 15 employees. These commenters explained that due to the small number of employees, small covered entities may have difficulty identifying an unbiased third-party employee to investigate and respond to grievances. For instance, commenters noted that it is not uncommon for the chief physician or other professional to serve as the compliance coordinator for a small covered entity, but that such a role would be inappropriate if that individual was the subject of a grievance. These commenters also observed that requiring a covered entity to handle internal grievances under Section 1557 might expose the entity to the risk of civil liability, because Section 1557 allows for private enforcement. These commenters recommended that OCR allow small covered entities flexibility in determining when to defer to outside counsel or other independent, unbiased

third parties to address grievances and thus mitigate their liability risk.

Response: We decline to extend the requirements of § 92.7 to covered entities with fewer than 15 employees. Although we recognize the benefits that extension of the requirements of § 92.7 would generate, we conclude that the costs, which would be borne by small entities, likely outweigh the benefits. Although many covered entities with fewer than 15 employees may have already identified a compliance coordinator and implemented a grievance policy to comply with the HIPAA Privacy Rule, extending the requirements of § 92.7 to such entities would create additional costs, as entities would need to revise their existing policies and retrain compliance coordinators.

Although we decline to extend the requirement of § 92.7 to covered entities with fewer than 15 employees, nothing in the final rule bars a covered entity with fewer than 15 employees from designating an employee to coordinate compliance with Section 1557 and this part or from adopting and implementing a grievance procedure. As we stated in the proposed rule, in OCR's experience, the presence of a coordinator and grievance procedure enhances the covered entity's accountability and helps bring concerns to prompt resolution, oftentimes prior to an individual bringing a private right of action.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.7 with one technical modification in § 92.7(a): We replaced the reference to the "Office for Civil Rights" with "Director," as § 92.4 defines "Director" to mean the Director of the Department's OCR. We have also added a sample grievance procedure as Appendix C to the final rule to provide covered entities an example of a grievance procedure that meets the requirements of § 92.7(b).

Notice Requirement (§ 92.8)

In § 92.8, OCR proposed that each covered entity take initial and continuing steps to notify beneficiaries, enrollees, applicants, or members of the public of individuals' rights under Section 1557 and this part and of covered entities' nondiscrimination obligations with respect to their health programs and activities. We modeled this section generally after the notice requirements found in regulations implementing Title VI, Title IX, Section 504, and the Age Act, which require

covered entities to have a notice in place.⁹⁶

Paragraphs (a)(1)–(7) of proposed § 92.8 identify the components of the notice. Specifically, paragraph (a)(1) proposed that the notice include that the covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability.

Paragraph (a)(2) proposed that the notice include a statement that the covered entity provides auxiliary aids and services, free of charge, in a timely manner, to individuals with disabilities, when such aids and services are necessary to provide an individual with a disability an equal opportunity to benefit from the entity's health programs or activities. Paragraph (a)(3) proposed that the notice state that the covered entity provides language assistance services, free of charge, in a timely manner, to individuals with limited English proficiency, when those services are necessary to provide an individual with limited English proficiency meaningful access to a covered entity's health programs or activities.

Paragraph (a)(4) proposed that the notice include information on how an individual can access the aids and services referenced in (a)(2) and (a)(3).

Paragraph (a)(5) proposed that the notice provide contact information for the responsible employee coordinating compliance with Section 1557 and this part, where such a responsible employee is required by § 92.7(a).

Paragraph (a)(6) proposed that the notice state that the covered entity has a grievance procedure where such a grievance procedure is required by § 92.7(b), and information on how to file a grievance.

Paragraph (a)(7) proposed that the notice provide information on how to file a complaint with OCR. We noted that inclusion of this requirement ensures that covered entities inform individuals about the enforcement mechanisms outside of the covered entity's internal process.

Proposed paragraph (b) stated that within 90 days of the effective date of this part, each covered entity shall post the notice required in § 92.8(a) in English, consistent with paragraph (f) of this section.

Paragraph (c) proposed that the Director shall make available a sample notice. We provided that covered

⁹⁵ See 45 CFR 164.520(b)(1)(vi) and § 164.530(a)(1)(ii) (requires designation of "contact person or office who is responsible for receiving complaints under this subsection" and the provision of a notice "that contains a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint," respectively.)

⁹⁶ 45 CFR 80.6(d) (requiring recipients to provide notice of individuals' rights under Title VI), 84.8(a)–(b) (requiring recipients to provide notice of individuals' rights under Section 504), 86.9(a)–(c) (requiring notice of individuals' rights under Title IX), 91.32 (requiring recipients to provide notice of individuals' rights under the Age Act).

entities may use this sample notice or may develop their own notices that convey the information in paragraphs (a)(1) through (7).

OCR invited comment on whether the proposed rule should permit covered entities to combine the content of the notice with the content of other notices that covered entities may be required to disseminate or post under Federal laws. OCR further invited comment on what steps covered entities may or should take to ensure that notices that combine the content required in § 92.8(a)(1)–(7) with other required notices do so without compromising the intent of § 92.8 to inform individuals of their civil rights under Section 1557 and this part. OCR also invited comment on whether the final rule should allow the notice to be modified for publications and other communication vehicles that may not have sufficient space to accommodate the full notice.

Paragraph (c) also proposed that the Director shall translate the sample notice into the top 15 languages spoken by individuals with limited English proficiency nationally and make the translated notices available to covered entities electronically and in any other manner the Director determines appropriate. We encouraged covered entities to post one or more of the translated notices that the Director provides and to make the notice available in non-English languages other than those provided by the Director. OCR sought comments on requiring, rather than merely encouraging, covered entities to post one or more of the notices in the most prevalent non-English languages frequently encountered by covered entities in their geographic service areas.

With regard to the proposal that the Director provide translations of the sample notice, we described that we selected the top 15 languages spoken by individuals with limited English proficiency nationally as a data driven policy.⁹⁷ We noted that we plan to review U.S. Census Bureau data as newer data become available to determine if and when the top 15 languages spoken nationally by individuals with limited English proficiency change, warranting the Director to make available notices in additional non-English languages.

Paragraph (d) proposed that within 90 days of the effective date of this part, each covered entity shall post, consistent with paragraph (f) of this section, taglines in at least the top 15 languages spoken nationally by

individuals with limited English proficiency. We requested comment on a sample tagline in Appendix B to the proposed rule.

Paragraph (e) proposed that the Director shall make available taglines in the top 15 languages spoken nationally by individuals with limited English proficiency for use by covered entities. OCR proposed this approach to maximize efficiency and economies of scale by enabling covered entities to receive the benefits of having multi-language taglines available without incurring the associated translation costs.

In paragraph (f), we proposed that covered entities must post the English-language notice required in § 92.8(a) and taglines required in § 92.8(d) in a conspicuously-visible font size in: Significant publications or significant communications targeted to beneficiaries, enrollees, applicants, or members of the public, which may include patient handbooks, outreach publications, or written notices pertaining to rights or benefits or requiring a response from an individual; in conspicuous physical locations; and in a conspicuous location on the home page of a covered entity's Web site. We sought comment on the scope of significant publications and significant communications.

We noted that covered entities that distribute significant publications or significant communications will need to update these publications to include the notice required in § 92.8(a) and taglines required in § 92.8(d). However, we proposed allowing entities to exhaust their current stock of hard copy publications rather than requiring a special printing of the publications to include the new notice.

We stated that covered entities may satisfy the requirement to post the notice on the covered entity's home page by including a link in a conspicuous location on the covered entity's home page that immediately directs the individual to the content of the notice elsewhere on the Web site. Similarly, we stated with regard to the requirement to post taglines that covered entities can comply by posting "in language" Web links, which are links written in each of the 15 non-English languages posted conspicuously on the home page that direct the individual to the full text of the tagline indicating how the individual may obtain language assistance services. For instance, a tagline directing an individual to a Web site with the full text of a tagline written in Haitian Creole should appear as "Kreyòl Ayisien" rather than "Haitian Creole."

In the proposed rule, we invited comment on a State-based methodology for identifying the languages in which covered entities would be required to post taglines and for which the OCR Director would be required to translate the notice. We explained that the top 15 languages spoken by individuals with limited English proficiency nationally can differ from the languages spoken most frequently by individuals within the areas served by covered entities' health programs and activities. Thus, we invited comment on a requirement for entities to make taglines available in the top 15 languages spoken State-wide, rather than nationwide, by individuals with limited English proficiency. This threshold aligns with Federal regulations governing the Health Insurance Marketplaces and qualified health plan issuers.⁹⁸

To reduce the burden on covered entities, proposed subsection (g) of this section stated that a covered entity's compliance with § 92.8 satisfies the notice requirements under HHS's Title VI, Section 504, Title IX, and Age Act regulations. We requested comment on this proposal.

The comments and our responses regarding § 92.8 are set forth below.

Comment: Some commenters suggested that we revise the information required in § 92.8(a)(1)–(7) regarding the notice of individuals' rights. For instance, some commenters suggested that we specify that Section 1557 prohibits discrimination on the basis of "national origin, including primary language and immigration status" and "sex, including pregnancy, gender identity, sex stereotypes, or sexual orientation. . . ." These commenters asserted that the addition of these terms would more completely reflect the scope of protected classes under Section 1557. A few commenters recommended that the notice inform individuals of any religious accommodations or exemptions that the covered entity has received from compliance with civil rights laws and explain the services that

⁹⁷ See 80 FR 54179 (describing the methodology used in the proposed rule).

⁹⁸ See 45 CFR 155.205(c)(2)(iii)(A). This regulation, which requires taglines on certain documents and Web site content in at least the top 15 languages spoken State-wide by individuals with limited English proficiency is not the only tagline requirement with which qualified health plan issuers must comply. Qualified health plan issuers must comply with another tagline requirement applicable to group health plans and health insurance issuers, which requires taglines, on certain notices and on a health plan's summary of benefits and coverage, in languages in which 10% of individuals with limited English proficiency county-wide are exclusively literate. See, e.g., 45 CFR 147.136(e)(2)(iii), (e)(3) (HHS regulations); 29 CFR 2590.715–2719(e)(2)(iii), (3) (DOL regulations for group health plans and health insurance issuers that are not grandfathered health plans).

the covered entity will and will not provide as a result of any religious exemptions or accommodations. Finally, a few commenters recommended revising §§ 92.8(a)(2) and (a)(3) to more closely parallel each other. For example, these commenters recommended that we list examples of language assistance services in paragraph (a)(3) and add a reference to providing meaningful access for persons with disabilities in paragraph (a)(2) of § 92.8.

Response: We decline to incorporate the suggestions made with regard to § 92.8(a)(1). The final rule defines the terms “on the basis of sex” and “national origin” in § 92.4, which is sufficient to define the scope of these protected classes as used in § 92.8(a)(1) and in Appendix A.⁹⁹ We are concerned that replicating the regulatory definitions of “on the basis of sex” and “national origin” in § 92.8(a)(1) and across-the-board in the final rule would dilute the concise, targeted message of the nondiscrimination statement and reduce the value of identifying the core bases on which discrimination is prohibited. Further, replicating the definitional text of these bases in § 92.8(a)(1) but not throughout the final rule may cause unnecessary confusion regarding the scope of discrimination prohibited by Section 1557 and this part. Accordingly, we decline to make the suggested revisions and are removing the terms “including sex stereotypes and gender identity” from the sample notice in Appendix A. OCR intended the nondiscrimination statement in § 92.8(a)(1) to convey covered entities’ overarching nondiscrimination obligations in a simple and streamlined manner, as the notice requirements do in regulations implementing Title VI, Title IX, Section 504, and the Age Act.¹⁰⁰ The notice requirement of the Title IX implementing regulations does not require recipients of Federal financial assistance to identify exclusions from Title IX’s application or exceptions to discrimination prohibited under Title IX.¹⁰¹ Moreover, under the final rule, the availability of a religious exemption will depend on an analysis of the particular situation; thus, it would be

difficult for an entity to state that it was exempt for all purposes. Accordingly, this final rule preserves the simplicity of the nondiscrimination statement consistent with other Federal civil rights laws.

We have revised § 92.8(a)(3) to list examples of language assistance services to parallel § 92.8(a)(2), which lists examples of auxiliary aids and services. We decline to modify the standards in paragraphs (a)(2) and (a)(3) because “meaningful access” is not the proper standard used in Section 504 for ensuring effective communication for individuals with disabilities.

Finally, as we stated in the proposed rule, Appendix A to part 92 is a sample notice. Covered entities are free to draft their own notices that convey the content in § 92.8(a)(1)–(7).

Comment: We received many comments addressing practical concerns about the size and length of required notices and taglines. Some commenters supported giving covered entities the flexibility to combine the content of the notice in § 92.8(a)(1)–(7) with other notices required under other Federal laws. For instance, a few comments stated that the State-based Marketplaces should be allowed to combine the content of the notice in § 92.8(a) with disclosures required by Federal regulations governing the Health Insurance Marketplaces at 45 CFR 155.230. Conversely, some commenters strongly opposed the idea of combining the content of the notice required in § 92.8(a) with other notices, reasoning that the combination, and likely modification, of the notice’s content would diminish the clear message of the notice.

Some commenters expressed concern that posting the notice and the taglines in a “conspicuously-visible font size” as proposed in § 92.8(f)(1) and a “conspicuous physical location” as proposed in § 92.8(f)(1)(ii) would occupy prohibitive amounts of space for covered entities operating in small physical spaces, such as pharmacies. These commenters suggested that OCR permit covered entities operating in smaller physical spaces to post taglines in fewer than 15 non-English languages. Other commenters requested clarification from OCR on what constitutes a “conspicuous physical location” in § 92.8(f)(ii) and “conspicuously visible font size” in § 92.8(f)(1).

A number of commenters recommended that the final rule require covered entities to post the notice of individuals’ rights—and not just taglines—in non-English languages.

Response: We intend to provide covered entities some flexibility to implement the requirements of § 92.8 in the manner that they determine meets the standards of this section while also reducing burden.

For instance, we will permit covered entities to combine the content of the notice in § 92.8(a)(1)–(7) with the content of other notices, such as notices required under other Federal civil rights laws. The content of the combined notice still must clearly convey the information required in § 92.8(a)(1)–(7) and must separately meet any applicable notice requirements under relevant legal authorities. For instance, the regulations implementing Title IX and Section 504 require that a recipient provide a notice of individuals’ rights to employees and applicants for employment.¹⁰² Because this final rule is limited in its application to employment, it may not be sufficient for an entity covered by Title IX, Section 504, and Section 1557 and this part to rely on a notice conveying the content required in § 92.8(a)(1)–(7) as meeting its notice obligations under the regulations implementing Section 504 and Title IX. Accordingly, proposed paragraph (g), which is now redesignated as paragraph (h) of this final rule, no longer treats an entity’s compliance with particular paragraphs of § 92.8 as constituting compliance with the notice provisions of other Federal civil rights authorities.

Specifically, § 92.8(h) now clarifies that covered entities may combine the content of the notice in § 92.8(a)(1)–(7) with the content of other notices as long as the combined notice clearly informs individuals of their civil rights under Section 1557 and this part. In addition to having flexibility with respect to combining notices, covered entities also have flexibility in determining the exact size and location of notices and taglines within their facilities as long as they do not compromise the intent of § 92.8 to clearly inform individuals of their civil rights under Section 1557 and this part.

The touchstone by which we will assess whether a covered entity’s provision of notice and taglines is effective is whether the content is sufficiently conspicuous and visible that individuals seeking services from, or participating in, the health program or activity could reasonably be expected to see and be able to read the information.

¹⁰² See 45 CFR 86.9(a)(1) (requiring a recipient to provide a notice of individuals’ rights to applicants for employment and to employees, among other groups of individuals); *id.* 84.8(a) (requiring a recipient to provide a notice of individuals’ rights requiring notice to employees, among other groups of individuals).

⁹⁹ An individual’s national origin is not the same as her citizenship or immigration status, and neither Title VI nor Section 1557 explicitly protects individuals against discrimination on the basis of citizenship or immigration status. However, as under Title VI, Section 1557 and this part protect individuals present in the United States, whether lawfully or not, who are subject to discrimination based on race, color, national origin, sex, age, or disability. See discussion *supra* note 53.

¹⁰⁰ *Supra* note 96.

¹⁰¹ 45 CFR 86.9(a).

Although we encourage covered entities to post the notice of individuals' rights in one or more of the most prevalent non-English languages frequently encountered by covered entities in their geographic service areas, we decline to require such posting in the final rule because of the resource burdens and opportunity costs to covered entities. Posted taglines sufficiently alert individuals to the language assistance services available and appropriately balance the educational value of the notices with the burdens to covered entities.

Given that we are not requiring covered entities to post notices in non-English languages, having taglines available in multiple languages is even more important to provide notice to individuals with limited English proficiency of the availability of language assistance services. Thus, we decline to reduce the number of languages in which taglines are required to appear, even for covered entities operating in smaller physical spaces. Covered entities have flexibility in determining the exact size and location of notices and taglines as long as they meet the requirements of this section.

Comment: We received many comments recommending alternative approaches to the proposed rule's requirement for taglines. A few commenters opposed the requirement in proposed § 92.8(d) as unnecessary because oral interpretation is generally available through the customer service telephone line listed on many consumers' health insurance cards. Some commenters suggested that the final rule should permit covered entities to include taglines on the inside of an envelope that a covered entity's health program or activity uses to mail a significant publication or a significant communication. A few commenters suggested replacing tagline text with an icon that would symbolize the availability of oral interpretation services. These commenters suggested that the icon would likely reach more language groups than taglines, and would also occupy substantially less space on significant publications and significant communications.

Response: We decline to eliminate the tagline requirement because such an approach would not provide adequate notice of language assistance services. We appreciate that many health insurance issuers provide telephonic oral interpretation services through their customer service lines/call centers—a number that usually appears on an insured individual's health insurance identification card. We do not, however, regard the mere availability of this

information as adequate notice to individuals with limited English proficiency of the availability of language assistance services, much less as notice of each of the components of paragraphs (a)(1)–(7) of § 92.8. Moreover, this approach is not appropriate in all instances because not all covered entities rely on the use of an individual identification card.

In addition, we decline to authorize placement of taglines on the inside of an envelope. Such a placement would diminish the visibility of the taglines, downgrade their importance, and fail to adequately notify individuals because envelopes are generally torn open and then discarded.

With respect to use of an icon, we appreciate the commenters' suggestion and believe that it may hold promise in the future. However, we also decline to require the use of an icon in the final rule. At this point in time, use of an icon alone would not provide consumers with sufficient notice of the availability of language assistance services, which is the intent of § 92.8(d).

Comment: A small number of commenters provided feedback on the application of the requirement to post the notice and taglines in significant publications and significant communications that are small in size, such as brochures, postcards, targeted fliers, small posters, and those that are communicated through social media platforms. Some commenters recommended that the final rule exempt such communications and publications from the posting requirement in § 92.8(f)(1)(i); others recommended that the final rule provide covered entities latitude to substantially shorten the notice and taglines for these publications and communications. Commenters advocating for either of these two positions stated that the limited amount of space in such publications and communications makes them an impractical medium for disclosures of civil rights.

Other commenters opposed any exceptions for significant publications and significant communications that are small-sized, given the importance of notifying individuals about their rights under Section 1557, such as how to obtain auxiliary aids and services for individuals with disabilities and how to obtain language assistance services for individuals with limited English proficiency.

Response: We agree that the notice and tagline requirements for small-sized significant publications and communications should be distinguished from the requirements for significant publications and significant

communications that are not small-sized. We also agree with commenters who suggested that small-sized significant publications and significant communications are not well-suited to extensive civil rights disclosures and that they function to drive consumers to other sources of information, such as a covered entity's Web site, where the full civil rights notice and taglines are required by § 92.8(f)(iii). Furthermore, posting the full notice and all 15 taglines to small-sized publications and communications may obscure the content and message of the document, thus undermining the value of such publication or communication. As a result, we are modifying § 92.8(f)(1)(i) to exclude small-sized significant publications and communications from requirements to have a notice and at least 15 taglines.

We disagree, however, with fully exempting significant publications and significant communications that are small-sized from the notice and tagline requirements because these documents, such as tri-fold brochures, pamphlets, and postcards, often serve as a gateway for an individual to apply for, or participate in, a particular health program or activity. To this end, the final rule establishes a separate requirement for small-sized significant publications and significant communications: A covered entity must include a nondiscrimination statement in lieu of the full notice, and taglines in two non-English languages in lieu of all 15 taglines, on small-size significant publications and significant communications.

Specifically, we moved most of the text from proposed paragraph (b) into a new paragraph (b)(1) and added paragraph (b)(2), which addresses the obligation to post a nondiscrimination statement that conveys the information in § 92.8(a)(1) on small-sized significant publications and significant communications. Similarly, we moved most of the text from proposed paragraph (d) into a new paragraph (d)(1) and added paragraph (d)(2), which addresses the obligation to post taglines in at least the top two languages spoken by individuals with limited English proficiency in the relevant State or States on small-size significant publications and significant communications. Finally, we re-designated proposed paragraph (g) as paragraph (h) and we added new paragraphs (g)(1)–(2) to address the posting standards applicable to small-sized significant publications and significant communications.

In choosing a lower threshold than at least the top 15 languages spoken by

individuals with limited English proficiency, we chose a concrete number of languages, rather than a threshold formulated as a percentage, because on average about two-thirds of the limited English proficient population in each State¹⁰³ is reached by the top two languages spoken by individuals with limited English proficiency in that State. Moreover, requiring a specific number of taglines makes the impact of the requirement predictable for all covered entities in planning how these two taglines, along with the nondiscrimination statement, will fit on their significant communications and significant publications that are small-sized. In almost all States, the top two languages spoken by individuals with limited English proficiency captures Spanish and the other most prevalent non-English language. This approach in paragraphs (b)(2), (d)(2), and (g)(1)–(2) of § 92.8 is more streamlined than requiring the full notice and all 15 taglines but still will inform the majority of individuals with limited English proficiency of their rights to be protected from discrimination under Section 1557 and this part.

In addition, we have added a sample nondiscrimination statement in Appendix A that conveys the information in § 92.8(a)(1), for which the Director will also provide translations. Accordingly, we have modified paragraph (c) of § 92.8 to state that the Director will provide translations of the sample nondiscrimination statement. The translations of the sample notice and sample nondiscrimination statement are for covered entities' discretionary use only—the final rule does not require the posting of the notice or nondiscrimination statement in non-English languages.

Comment: A substantial majority of commenters on § 92.8 provided feedback on the methodology for determining the number of languages in which covered entities will be required to post taglines. Some commenters supported the proposed rule's national methodology because of its simplicity, particularly for covered entities that operate in multiple States. Conversely, other commenters expressed concern that the national standard fails to account for concentrations of particular limited English proficient communities

within areas served by covered entities' health programs and activities, including Native American languages spoken by those served in Tribal health programs. One commenter recommended that if the final rule includes a national standard, OCR should require taglines in the top 25 languages spoken nationally by individuals with limited English proficiency. This commenter further recommended that when calculating the top 25 languages, OCR should rely on a data set that “unbundles” bundled language groups, such as “other Asian languages,” because some languages represented in bundled categories may be highly prevalent in the service area of a particular covered entity's health program or activity.¹⁰⁴

Most commenters disfavoring a national methodology recommended that the languages in which covered entities must post taglines should be the top 15 languages spoken State-wide by individuals with limited English proficiency. Commenters explained that the State-wide threshold would be more attuned to the diversity of languages spoken by individuals with limited English proficiency in each State and would align with Federal regulations governing the Marketplaces and qualified health plan issuers.¹⁰⁵ Some of these commenters also recommended that the final rule should require covered entities that serve individuals in multiple States to post more than 15

¹⁰⁴ In October 2015, for the second time since the U.S. Census Bureau's American Community Survey (ACS) began, the Census Bureau released detailed tables that unbundle the 39 languages and language groups that ACS publishes annually through its American Factfinder data set. U.S. Dep't of Commerce, U.S. Census Bureau, Data, Detailed Languages Spoken at Home and Ability to Speak English for the Population 5 Years and Over: 2009–2013, <http://www.census.gov/data/tables/2013/demo/2009-2013-lang-tables.html> [hereinafter U.S. Census Bureau, ACS 2009–2013 Detailed Languages] (last visited May 3, 2016). The unbundled data includes 380 possible languages or language groups spoken by individuals who speak English less than “very well.” In the proposed rule, HHS explained that it calculated the top 15 languages spoken nationally by individuals with limited English proficiency by relying on the American Factfinder data set that bundles languages. See 80 FR 54172, 54179 n.30 (Sept. 8, 2015) (describing the tagline methodology).

¹⁰⁵ 45 CFR 155.205(c)(iii)(A) (beginning no later than November 1, 2016, requiring taglines on Web site content and documents that are critical for obtaining coverage or access to health care services through a qualified health plan for certain individuals in at least the top 15 languages spoken by individuals with limited English proficiency in the relevant State; documents are deemed to be critical for obtaining health insurance coverage or access to health care services through a qualified health plan if they are required to be provided by law or regulation to certain individuals); see *infra* note 107 (describing other tagline requirements applicable to qualified health plan issuers as a result of market-wide regulations).

taglines if the composite list of each State's list aggregates to a total of more than 15 languages. These commenters reasoned that such an interpretation is necessary to further the purpose of addressing the diversity of languages spoken by individuals with limited English proficiency served by a particular covered entity.

Other commenters recommended other approaches, such as requiring taglines in languages in which at least 10% of individuals with limited English proficiency county-wide are exclusively literate,¹⁰⁶ or, in languages spoken by at least 5% of individuals with limited English proficiency or 500 individuals with limited English proficiency in the covered entity's service area, whichever yielded the greater number of languages. Still other commenters recommended that the rule allow covered entities to choose between a State-wide and a national methodology in determining the languages in which to post taglines, depending on the geographic scope of the intended audience for the “significant publication or significant communication” to which the taglines are posted. These commenters explained that a covered entity that operates nationally may choose to post on the covered entity's Web site taglines in languages based on a nationwide threshold but may choose to include on a significant communication to an individual taglines in languages based on a State-wide threshold for the State in which the individual resides.

Response: In response to commenters' recommendations, § 92.8(d)(1) of the final rule requires covered entities to post taglines in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States. Accordingly, paragraphs (d)(1)–(2) of § 92.8 refer to this State-based methodology rather than a national methodology. This threshold captures, on average, 90% of each State's LEP population.

We adopt a State-based approach for three main reasons. First, a State-based methodology is more attuned to the diversity of languages spoken by individuals with limited English proficiency and thus provides notice to more individuals with limited English proficiency.

Second, this State-wide approach better harmonizes with the number of languages in which taglines must be provided by Marketplaces and qualified health plan issuers under 45 CFR

¹⁰⁶ This 10% county-level threshold for taglines applies to group health plans and health insurance issuers. See, e.g., 45 CFR 147.136(e)(2)(iii), (e)(3) (HHS regulations); 29 CFR 2590.715–2719(e)(2)(iii), (3) (DOL regulations).

¹⁰³ In estimating this percentage, we used the same data sources, *infra* notes 109 and 110, and the same methodology described in the discussion, *infra*, that we used to identify the languages under the State-based approach in which the Director will translate the sample notice and taglines, as required by § 92.8(c) and (e) of the final rule.

155.205(c)(2)(iii)(A).¹⁰⁷ Section 92.8 of this final rule applies to all entities covered by Section 1557, but for Marketplaces and qualified health plan issuers that are subject to the tagline requirements at 45 CFR

155.205(c)(2)(iii)(A) and § 92.8 of this final rule, our State-wide methodology lessens the burden to which Marketplaces and qualified health plan issuers might otherwise be subject.

Third, a county-level approach is impractical because detailed language data are not available for counties with populations of less than 100,000. For counties with populations of at least 100,000 for which detailed language data are available, there are limited data for individuals who speak English less than “very well” and speak a non-English language other than Spanish.¹⁰⁸ For county-level data that are available, moreover, we are concerned that sampling error would render many estimates of small language populations unreliable when assessed within the small geographic area of a county.

With regard to the data used to identify the languages under the State-based methodology in which the Director will translate the sample notice, sample nondiscrimination statement, and taglines, as required by § 92.8(c) and (e) of the final rule, we rely on the most recent bundled and

unbundled five-year¹⁰⁹ data available from the U.S. Census Bureau. We rely on the data set that estimates the prevalence of foreign-language speakers who speak English less than “very well,”¹¹⁰ and we made technical adjustments, such as to remove any spoken languages that do not have a written equivalent in which the Director could translate a tagline.

We intend the threshold’s application in § 92.8(d)(1)–(2), which applies to the “relevant State or States,” to permit covered entities that serve individuals in more than one State¹¹¹ to aggregate the number of individuals with limited English proficiency in those States to determine the top 15 languages required by § 92.8(d)(1), or the top 2 languages required by § 92.8(d)(2) where each respective provision applies.¹¹² The languages produced from this aggregation are static with respect to the posting requirement in § 92.8(f). Using one of the three posting methods as an example—the posting of the taglines in a covered entity’s physical locations required by § 92.8(f)(1)(ii)—a covered entity that operates multiple health programs serving individuals within various States, or that operates a health program with a multi-State service area, complies with § 92.8(f)(1)(ii) when it posts, in its physical locations across the States it serves, taglines in at least the top 15 languages spoken by the aggregate limited English proficient

populations of those States, rather than of each individual State. We do not intend to require a covered entity that operates health programs in multiple States (or in States nationwide), or that administers a health program with a multi-State service area (or even a nationwide service area), to tailor the taglines for the specific State in which the entity is physically located or in which an individual with limited English proficiency, with whom the entity communicates, lives. This interpretation best balances the burden on covered entities with the notification of language assistance services to individuals required by § 92.8(d).¹¹³

We reiterate, however, that the requirements of § 92.8(d)(1)–(2) establish a floor; covered entities are free to include taglines in additional languages beyond 15 languages. For instance, a covered entity that has chosen to aggregate languages may choose to post taglines in all languages on the aggregated list rather than posting just the top 15 languages. Moreover, a covered entity that that operates health programs in multiple States or that administers a health program with a multi-State service area may decide not to aggregate. Instead, the entity may choose to tailor the taglines posted in its physical locations for the specific State in which the physical location exists; similarly, the entity may choose to tailor the taglines on a certain significant communication based on the State in which an individual with limited English proficiency, with whom the entity communicates, lives.

In addition, we note that complying with § 92.8(d)(1)–(2) is not a substitute for complying with the prohibition of national origin discrimination as it affects individuals with limited English proficiency under Section 1557 or this part, including the general nondiscrimination provisions in § 92.101 and the meaningful access provisions in § 92.201 of this final rule. Thus, although this section identifies the languages in which covered entities must post taglines, it does not relieve those entities of the separate obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency who communicate in other languages.

Comment: One commenter recommended including American Sign

¹⁰⁷ Qualified health plan issuers are also bound by the tagline requirement in market-wide regulations at 45 CFR 147.136(e). Under § 147.136(e), taglines must appear on certain notices and on a health plan or issuer’s summary of benefits and coverage, in languages in which 10% of individuals with limited English proficiency county-wide are exclusively literate. *See, e.g.*, 45 CFR 147.136(e)(2)(iii), (e)(3). This methodology applies to a narrower set of documents than those to which the tagline requirement applies in Federal regulations governing Marketplaces and qualified health plan issuers. *Compare* 45 CFR 147.136(e)(2)(iii) (requiring taglines on internal claims and appeals notices) *and* 45 CFR 147.200(a)(5) (requiring taglines on summaries of benefits and coverage) *with* 45 CFR 155.205(c)(2)(iii)(A) (requiring taglines on Web site content and documents that are critical for obtaining health insurance coverage or access to health care services through a qualified health plan). For CMS’s most recent technical guidance on the tagline requirement at 45 CFR 155.205(c)(2)(iii)(A), *see* Guidance and Population Data for Exchanges, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and 156.250 (Mar. 30, 2016), <https://www.cms.gov/ccio/resources/regulations-and-guidance/index.html#>, Language Access Guide for Exchanges, Qualified Health Plan (QHP) Issuers, and Web-Brokers (last visited May 3, 2016).

¹⁰⁸ U.S. Census Bureau, ACS 2009–2013 Detailed Languages, *supra* note 104 (detailing data parameters in the user notes). At least 25,000 individuals who speak English less than “very well” must speak the same language for the ACS county-level data to identify such language speakers. *Id.*

¹⁰⁹ We rely on the American Community Survey (ACS) 5-year data set because its stability is superior to the 1-year data set, especially when analyzing small populations. U.S. Census Bureau, American Community Survey, When to Use 1-year, 3-year, or 5-year Estimates, <http://www.census.gov/programs-surveys/acs/guidance/estimates.html> (last visited May 3, 2016). The U.S. Census Bureau has discontinued the ACS 3-year data set, which is the data set on which we relied in the proposed rule. U.S. Census Bureau, Census Bureau Statement on the 3-Year American Community Survey Statistical Product (Feb. 2, 2015), <http://content.govdelivery.com/accounts/USCENSUS/bulletins/eeb4af> (last visited May 3, 2016).

¹¹⁰ U.S. Dep’t of Commerce, U.S. Census Bureau, American FactFinder, Language Spoken at Home by Ability to Speak English for the Population 5 Years and Older, ACS Estimates by State: 2010–2014 (released Dec. 2015); U.S. Census Bureau, ACS 2009–2013 Detailed Languages, *supra* note 104. We are not aware of a public data source providing as robust data as the ACS that estimates the languages in which individuals with limited English proficiency read, understand, or speak. Thus, we are relying on a data set identifying individuals who have a limited ability to speak English as a proxy for limited English proficiency population.

¹¹¹ This categorization includes covered entities that operate multiple health programs serving individuals within various States or that operate a health program with a multi-State service area.

¹¹² For a similar approach, *see* HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 FR 10750, 10788 (Feb. 27, 2015) (describing the Department’s interpretation of 45 CFR 155.205(c)(2)(iii)(A) and (B) for entities with multi-State service areas).

¹¹³ As newer ACS data become available with respect to the data sets on which we base our methodology, we will determine if and when the at least top 15 languages spoken by individuals with limited English proficiency State-wide change, warranting the Director to make available notices and taglines translated in additional non-English languages.

Language as a language for which a posted tagline be required in § 92.8(d). This commenter stated that taglines denoting the availability of American Sign Language Interpretation could communicate this message by displaying still images, rather than a written language.

Response: We decline to include American Sign Language as a language for which a tagline is required in § 92.8(d)(1)–(2) because the notice of individuals’ rights in § 92.8(a)(2), which must be posted in a conspicuously-visible font size and location just like taglines, addresses this issue.

Specifically, paragraph (a)(2) requires that the notice of individuals’ rights state that the covered entity provides auxiliary aids and services, which include sign language interpreters, to individuals with disabilities when necessary to provide such individuals an equal opportunity to benefit from the entity’s health programs or activities.

Comment: A few commenters recommended that the final rule prescribe the location of taglines at or near the beginning of significant publications and significant communications. These commenters provided anecdotal evidence that individuals with limited English proficiency who received multi-page English notices requiring time-sensitive responses failed to see taglines appearing on the last page. Commenters explained that to the individuals’ detriment, they discarded the notices without responding, resulting in termination of health insurance coverage and other negative outcomes. A number of commenters recommended that covered entities be required to include the text of all required taglines, not just the in-language link, conspicuously on the homepage of their Web sites.

Response: Although we encourage covered entities to include notices and taglines at the beginning of significant publications and significant communications to ensure that they are meaningfully accessible to the consumer, we decline to require this prescriptive approach as part of the final rule. In some circumstances, such as lengthy publications, it may be necessary to include the notice and taglines at the beginning of a document to meet the requirements of § 92.8(f)(1)(i) and (g)(1)–(2); in others, posting elsewhere, including on a separate insert¹¹⁴ accompanying the

English-language significant publication or significant communication, may be adequate. Furthermore, in today’s increasingly electronic and digital age where covered entities may make their first impressions through Web content (often on small mobile devices), we are sensitive to covered entities’ need for autonomy in designing and managing the appearance of their public internet home pages.

Although the law requires that individuals receive sufficient notice of language assistance services available to assist individuals with limited English proficiency in understanding the content of a covered entity’s Web site, we believe that the use of in-language links permitted under this provision of the proposed rule is the approach that best balances notice to individuals against burden to covered entities.

Comment: Some commenters described the proposed requirement to post the notice in “significant publications and significant communications” as onerous. One commenter recommended that health plans provide the notice to individuals on an annual basis, along with individuals’ annual enrollment package, instead of on each “significant publication and significant communication.” Some commenters requested that OCR include, in regulation text, the examples of “significant publications and significant communications” we provided in the preamble to the proposed rule, specifically outreach publications and patient handbooks. A few commenters requested that OCR consult with other Federal agencies on the scope of “significant publications and significant communications” to establish a common understanding of this term so that covered entities whose publications and communications are regulated by more than one Federal agency are not subject to conflicting standards.

Other commenters were concerned about OCR’s statement in the preamble of the proposed rule that OCR intended the scope of “significant publications and significant communications” to include not only documents meant for the public but also individual letters or notices to an individual, such as a letter to a consumer notifying the individual of a change in benefits. These commenters observed that, pursuant to existing Federal and State law, many

documents or as a separate page included with certain documents. U.S. Dep’t of Health & Human Servs., Centers for Medicare & Medicaid Servs., Medicare Marketing Guidelines, § 30.5.1, 7–8 (Jul. 2, 2015), <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html>.

letters already include disclosures and other legally mandated information; consequently, the requirement to post both the notice and taglines required in proposed § 92.8(a) and (d), respectively, might dilute the primary message of the letter and confuse or frustrate consumers. Some commenters requested clarification on how “vital documents” as used in the Department’s LEP Guidance relates to “significant publications and significant communications” in § 92.8(f)(1)(i) of the proposed rule.

Response: We disagree with commenters’ characterization of § 92.8(f)(1)(iii) as “onerous.” We acknowledge that compliance with this subsection may impose some limited burdens on covered entities. However, these burdens are outweighed by the benefits that § 92.8(f)(1)(iii) will generate for individuals with limited English proficiency by making them aware, in their own languages, of the availability of language assistance services. Notifying individuals of their rights under Section 1557 and this part, including the availability of language assistance services for individuals with limited English proficiency and the availability of auxiliary aids and services for persons with disabilities, is critical to providing an equal opportunity to access health care and health coverage. For these reasons, OCR intends to interpret “significant communications and significant publications” broadly, which is consistent with the notice provisions of other Federal civil rights authorities, such as Section 504¹¹⁵ and Title IX.¹¹⁶

We decline to limit the posting requirement in § 92.8(f)(iii) to an annual frequency. The notice requirements in other Federal civil rights laws on which we modeled § 92.8 do not contain a similar limitation. Moreover we also note that not every covered entity sends annual notices.

¹¹⁵ 45 CFR 84.8(a)–(b) (indicating that methods of notifying individuals’ of their rights under Section 504 may include “publication in newspapers and magazines, placement of notices in [Federal financial assistance] recipients’ publication[s], and distribution of memoranda or other written communications” as well as “recruitment materials or publications containing general information that . . . [the recipient] makes available to participants, beneficiaries, [and] applicants. . . .”).

¹¹⁶ 45 CFR 86.9(a)(2)(i) (requiring initial notice of individuals’ rights to appear in local newspapers, newspapers and magazines published by the recipient of Federal financial assistance, and “memoranda or other written communications distributed to every student . . . of such recipient”) and 86.9(b)(1) (requiring each recipient of Federal financial assistance to “prominently include a statement of . . . [the recipient’s nondiscrimination policy] in each announcement, bulletin, catalog, or application form which it makes available . . .”).

¹¹⁴ For instance, Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, and Medicare Prescription Drug Plans must include a “CMS Multi-Language Insert” in the text of certain

We also decline to enshrine a list of examples of “significant publications and significant communications” in regulation for two main reasons. First, the final rule applies to such a diverse range of covered entities that codifying examples likely would not provide meaningful guidance to the full spectrum of covered entities regulated. Second, we intend to maximize covered entities’ flexibility, and each covered entity is in the best position to determine which of its communications and publications with respect to its health programs and activities are significant.

In response to commenters who requested that “significant publications and significant communications” be limited to documents intended for the public, rather than those intended for specific individuals, we decline to limit the intended scope of such documents to those aimed only at the public at-large. We intend the scope of significant publications and significant communications to include not only documents intended for the public, such as outreach, education, and marketing materials, but also written notices requiring a response from an individual and written notices to an individual, such as those pertaining to rights or benefits. We have no reasoned basis to distinguish and exempt significant publications and significant communications intended for specific individuals from significant publications and significant communications intended for the public at-large. Indeed, in some situations, a written notice with information tailored to a specific individual’s benefits or participation may be even more important to that individual than a significant publication or significant communication conveying information to the public. Accordingly, an individual’s awareness of his or her rights under Section 1557, such as the availability of auxiliary aids and services for persons with disabilities (required in § 92.8(a)(2) to be in the nondiscrimination notice) is just as important as information communicated to the public at-large.¹¹⁷

¹¹⁷ For comparison, the meaningful access requirements of other Federal regulations governing qualified health plan issuers apply to all information that is critical for obtaining health insurance coverage or access to health services through the qualified health plan, including “applications, forms, and notices” and information is deemed to be critical for obtaining health insurance coverage or access to health care services if the issuer is “required by law or regulation” to provide the document to certain individuals. See 45 CFR 156.250. CMS’s annual guidance to qualified health plan issuers lists examples of documents to which CMS interprets § 156.250 to apply, such as

The HHS LEP Guidance uses the term “vital documents” to refer to the documents for which covered entities should prioritize written translations for individuals with limited English proficiency.¹¹⁸ The HHS LEP Guidance does not define vital documents. Rather, the Guidance states that “[w]hether or not a document (or the information it solicits) is ‘vital’ may depend upon the importance of the program, information, encounter, or service involved, and the consequence to the LEP person if the information in question is not provided accurately or in a timely manner.”¹¹⁹ The HHS LEP Guidance also provides examples of documents likely to be “vital,” such as “consent and complaint forms, . . . [] written notices of eligibility criteria, rights, denial, loss, or decreases in benefits or services . . . [] [and] [a]pplications to participate in a recipient’s program or activity or to receive recipient benefits or services.”¹²⁰

OCR intends for “vital documents” to represent a subset of “significant communications and significant publications” in which covered entities must post the notice (or nondiscrimination statement in § 92.8(b), where applicable) and taglines required by § 92.8(d) and (f), among other electronic and physical locations. In clarifying this point, we emphasize that the HHS LEP Guidance uses the term “vital documents” to address how a covered entity should meet its Title VI obligations to translate entire documents. By contrast, we refer to “significant communications and significant publications” in this rule to identify the documents in which covered entities are required to post the notice of individuals’ rights (or nondiscrimination statement, where applicable) and taglines. We are not adopting an across-the-board requirement for covered entities to translate certain written documents into a threshold number of languages.

Comment: Some commenters recommended that OCR provide funding and other resources to non-profit organizations for the purpose of creating a national social media

certain correspondence and notifications, summary of benefits and coverage disclosures, formulary drug lists, provider directories, and a plan’s explanation of benefits or similar claim processing information. U.S. Dep’t of Health & Human Servs., Centers for Medicare & Medicaid Servs., Final 2017 Letter to Issuers in the Federally-facilitated Marketplaces, 80–81 (Feb. 29, 2016), <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf>.

¹¹⁸ HHS LEP Guidance, *supra* note 49, 68 FR at 47318–19.

¹¹⁹ *Id.* at 47318.

¹²⁰ *Id.* at 47319.

campaign to publicize the requirements of Section 1557.

Response: It is beyond scope of the final rule for OCR to fund organizations’ education and outreach efforts. OCR continues, however, to conduct outreach and provide technical assistance to inform covered entities of their obligations and individuals of their rights under Federal civil rights laws, including Section 1557 and this part. OCR will continue to disseminate, via web and social media platforms, fact sheets and other useful materials to covered entities and individuals.

Comment: OCR received a number of comments suggesting revisions to the sample notice in Appendix A and the sample tagline in Appendix B to the proposed rule, such as revisions to improve adherence to plain language writing principles. For example, with respect to the sample notice, a few commenters recommended revisions with respect to the provision of language assistance services: Adding the word “qualified” prior to the word “interpreters,” which is listed as a type of language assistance service; replacing “first language” with “primary language”; replacing “translated into other languages” with “written in other languages”; and deleting “when needed to communicate effectively with us.”

One commenter objected to the conditional tense of the sample tagline in Appendix B, which stated that “[i]f you speak [insert language], language assistance services may be available to you . . .,” expressing concern that it might deter an individual from asking for or about language assistance services. In addition, commenters suggested that the conditional phrasing of “may be available” is inconsistent with covered entities’ obligations under § 92.201 to take reasonable steps to provide meaningful access to each individual with limited English proficiency.

A few commenters recommended that the sample tagline in Appendix B be shortened but offered no specific recommendations on shorter language. Some commenters suggested that OCR consumer test the sample notice in Appendix A of the proposed rule before providing it as a sample in the final rule.

Response: We share commenters’ views that the sample notice should clearly convey civil rights information, which can often be complex. We agree with the specific revisions from commenters to improve the sample notice’s statement about a covered entity’s provision of language assistance services. We have modified Appendix A to the final rule to reflect these

revisions, and have made technical revisions to include OCR's contact information for filing a complaint. In our view, the sample notice, with these modifications, adequately apprises individuals of their civil rights under Section 1557 and this part without providing irrelevant or confusing information. We remind covered entities that nothing in the final rule prohibits covered entities from drafting their own notices to meet the requirements of § 92.8(a)(1)–(7), which covered entities are free to consumer test.

In addition, we have added a nondiscrimination statement to Appendix A that covered entities can post on significant publications and significant communications that are small-sized.

We appreciate commenters' attention to the details of the sample tagline's phrasing. We have modified Appendix B to the final rule to address commenters' concerns that the tagline's conditional wording might deter an individual from asking for or about language assistance services. With technological advancements in language assistance services, we are confident that covered entities have the ability, at a minimum, to obtain qualified oral interpretation services in the languages in which covered entities will provide taglines, consistent with § 92.8(d)(1)–(2); thus, the sample tagline as modified states that language services "are" available. In addition, we replaced the word "contact" with "call" to simplify the vocabulary used for average literacy levels. The modifications we have made amplify taglines' function as a critical gateway to language assistance services. Taglines derive value not only from informing individuals with limited English proficiency of language assistance services but also from prompting individuals to contact the covered entity to obtain language assistance. We decline to shorten the sample tagline because we are concerned that doing so would compromise the tagline's message and intent. We remind covered entities that Appendix B is a sample; covered entities are free to develop their own taglines as long as they provide taglines consistent with § 92.8(d)(1)–(2) of this part.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we have modified § 92.8 and Appendices A and B to part 92 as follows:

In § 92.8(a), we made technical modifications to paragraph (a) and paragraphs (a)(1)–(3). In paragraph (a)

we replaced the conjunction "or" with "and." In paragraph (a)(1), we clarified that the nondiscrimination statement of the notice applies to the health programs and activities of a covered entity. In paragraph (a)(2), we inserted the phrase "for individuals with disabilities" after "qualified interpreters" because the final rule now defines qualified interpreters for individuals with disabilities separately from qualified interpreters for individuals with limited English proficiency. In paragraph (a)(3), we added examples of language assistance services to promote alignment with paragraph (a)(2), which provides examples of auxiliary aids and services.

Most of the text in proposed § 92.8(b) is now reflected in new paragraph (b)(1). We added paragraph (b)(2) that requires a covered entity to post a nondiscrimination statement consistent with newly-designated paragraph (g)(1), which applies to significant publications and significant communications that are small-sized. In newly-designated paragraph (b)(1) and (f)(1), we eliminated "English-language" before "notice" to avoid the incongruous result that a significant publication or significant communication written in a non-English language must include a notice written in English.

In § 92.8(c), we added language to convey OCR's plans to translate the sample nondiscrimination statement for covered entities to use at their discretion.

In paragraph (d) of § 92.8, we added paragraph designations (1) and (2) to distinguish the final rule's tagline requirements for significant publications and significant communications that are not small-sized from those that are small-sized. Most of the text in proposed paragraph (d) is now reflected in paragraph (d)(1). In newly-designated (d)(1), we replaced the national threshold with a threshold requiring taglines in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States. In addition, we added a reference to the posting requirement in paragraph (f)(1) of § 92.8 for clarity. Paragraph (d)(2) identifies the tagline requirement for significant publications and significant communications that are small-sized. In paragraphs (c) and (e) of § 92.8, we replaced the national threshold with a reference to the languages triggered by the State-wide methodology described in paragraph (d)(1).

In § 92.8(f), we revised paragraph (f)(1) and paragraphs (f)(1)(i) and (iii). Specifically, in paragraph (f)(1), we

made a technical revision to remove an errant reference to paragraph (b) and we replaced the reference to paragraph (d) with (d)(1) to conform to the new paragraph designations of the final rule. In § 92.8(f)(1)(i), we replaced the conjunction "or" with "and" as a technical revision to align the text with the same technical revision in § 92.8(a). In addition, we excluded publications and significant communications that are small-sized from the requirement to post the notice conveying all content in § 92.8(a)(1)–(7) and from the requirement to post all 15 taglines. In paragraph (f)(1)(iii), we clarified the location of the tagline when posted to the covered entity's Web site.

We re-designated paragraph (g) in the proposed rule as paragraph (h) in this final rule. In the final rule, paragraph (g) addresses covered entities' requirements to post a nondiscrimination statement and taglines in significant publications and significant communications that are small-sized. Specifically, paragraph (g)(1) addresses the requirement to post a nondiscrimination statement and paragraph (g)(2) addresses the requirement to post taglines.

Newly re-designated paragraph (h) no longer treats an entity's compliance with particular paragraphs of § 92.8 as constituting compliance with the notice provisions of other Federal civil rights authorities. We revised the paragraph to address a covered entity's permissive authority to combine the content of the notice in paragraphs (a)(1)–(7) of this section with the content of other notices.

In Appendix A to the final rule, we made the following changes to improve the plain language reading of the sample notice and to streamline the sample notice's messaging:

- Deleted "sex stereotypes and gender identity" from the end of the first sentence;
- Replaced "worse" with "differently," and deleted the pronoun "their" prior to listing the bases on which the covered entity does not discriminate;
- Replaced "first language" with "primary language";
- Deleted "when needed to communicate effectively with us";
- Added "qualified" to modify "interpreters" with respect to serving individuals with limited English proficiency;
- Replaced "translated into other languages" with "written in other languages";
- Added placeholders for a covered entity to provide not only the name of its civil rights coordinator but also the individual's title; and

- Added contact information for filing a complaint with OCR.

In addition, we added a sample nondiscrimination statement in Appendix A for covered entities to post in significant publications and significant communications that are small-sized and accordingly broadened the title of Appendix A to reflect its revised scope.

In Appendix B to the final rule, we modified the language by replacing “may be available” with “are available” and by adding language to improve the plain language reading of the sample tagline, by replacing “[c]ontact” with “call.”

Subpart B—Nondiscrimination Provisions

Subpart B of the final rule incorporates regulatory provisions implementing the application of the civil rights statutes referenced in Section 1557(a): Title VI, Title IX, the Age Act, and Section 504.

Discrimination Prohibited (§ 92.101)

We proposed that § 92.101 of subpart B prohibit discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity to which Section 1557 or this part applies. We proposed that paragraphs (a) and (b) follow the structure of the implementing regulations for Title VI, Section 504, Title IX, and the Age Act by including a general nondiscrimination provision in paragraph (a) followed by a provision identifying specific discrimination prohibited in paragraph (b). In paragraph (c), we proposed to address exceptions to discrimination prohibited under the Title VI, Section 504, and Age Act regulations. We proposed that paragraph (d) effectuate technical changes in terminology to apply the provisions incorporated from other regulations to the covered entities obligated to comply with this proposed rule.

In paragraph (a)(1) of § 92.101 of the proposed rule, we restated the core objective of Section 1557(a), which prohibits discrimination on the grounds prohibited under Title VI (race, color, or national origin), Title IX (sex), the Age Act (age), or Section 504 (disability) in any health program or activity to which this part applies.

In paragraph (a)(2), we proposed to limit the ways in which the proposed rule applies to employment. We noted that except as provided in § 92.208, which addresses employee health benefit programs, the proposed rule does not generally apply to discrimination by a covered entity

against its own employees. Thus, the proposed rule would not extend to hiring, firing, promotions, or terms and conditions of employment outside of those identified in § 92.208; such claims could continue to be brought under other laws, including Title VII, Title IX, Section 504, the ADA and the Age Discrimination in Employment Act,¹²¹ as appropriate. We invited comment on our proposal to exclude these forms of employment discrimination from the scope of the proposed rule.

We proposed that paragraph (b) incorporate into the regulation the specific discriminatory actions prohibited by each civil rights statute which Section 1557 references. We considered harmonizing each of the specific discriminatory actions prohibited across each civil rights law addressed by Section 1557. We noted that although harmonization could reduce redundancy in the specific discriminatory actions incorporated that are similar to one another, harmonization would likely lead to confusion and unintended differences in interpretation that are subtle yet significant. We therefore proposed that paragraphs (b)(1)–(4) incorporate the specific discriminatory actions prohibited under each civil rights law on which Section 1557 is grounded. We sought comment on this proposed approach.

We proposed that paragraph (b)(1) adopt the specific discriminatory actions prohibited by the Title VI implementing regulation, which appear at 45 CFR 80.3(b)(1)–(6).

In paragraph (b)(2)(i), we proposed to address the specific prohibition of discrimination on the basis of disability with which recipients and State-based Marketplaces must comply. In paragraph (b)(2)(i), we proposed to adopt relevant provisions in the Section 504 implementing regulation for federally assisted programs and activities at 45 CFR part 84. We provided that the provisions incorporated are the specific discriminatory actions prohibited at § 84.4(b); the program accessibility provisions at §§ 84.21 through 84.23(b); and the provisions governing education, health, welfare, and social services at §§ 84.31, 84.34, 84.37, 84.38, and 84.41–84.55.

We proposed that paragraph (b)(2)(ii) address the specific prohibitions of discrimination on the basis of disability with which the Department, including the Federally-facilitated Marketplaces, must comply. We proposed that this paragraph adopt relevant provisions in

the Section 504 implementing regulation for federally administered programs and activities at 45 CFR part 85. We provided that the provisions adopted are the specific discriminatory actions prohibited at § 85.21(b) and the program accessibility provisions at §§ 85.41 through 85.42 and 84.44 through 84.51.

We proposed that paragraph (b)(3) adopt the specific discriminatory actions prohibited by the Title IX implementing regulation, which appear at 45 CFR 86.3(b)(1) through (8).

We also proposed that paragraph (b)(4) adopt the specific discriminatory actions prohibited by the Age Act implementing regulation, which appear at 45 CFR 91.11(b).

In paragraph (b)(5), we proposed that the specific discriminatory actions prohibited in § 92.101(b)(1) through (4) do not limit the general prohibition of discrimination in § 92.101(a). We noted that this statement is consistent with regulatory provisions in the implementing regulations for Title VI at 45 CFR 80.3(b)(5) and the Age Act at 45 CFR 91.11(c).

In paragraph (c), we proposed to incorporate the exceptions to the general prohibition of discrimination that appear in the implementing regulations for Title VI, Section 504, and the Age Act, as these exceptions have applied to health programs and activities for nearly 40 years. We noted that, generally, the exceptions in the Title VI, Section 504, and Age Act implementing regulations provide that it is not discriminatory to exclude a person from the benefits of a program that Federal law limits to a protected class. We did not address the sex-based distinctions authorized in Title IX and its implementing regulation in the context of education programs or activities. We noted that these distinctions do not necessarily apply in the health care context. However, we also noted that Title IX and the Department of Education’s Title IX regulations allow some single-sex education programs when certain requirements are met.¹²² We did not propose to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex, but sought comment on what other sex-based distinctions, if any, should be permitted in the context of health programs and activities and the standards for permitting the distinctions.

Finally, we proposed that paragraph (d) effectuate technical changes to apply

¹²¹ 29 U.S.C. 621–634.

¹²² 34 CFR 106.34.

the provisions incorporated in § 92.101(b) and (c) to covered entities obligated to comply with the proposed rule by, among other things, replacing references to “recipient” in the incorporated provisions with “covered entity.”

The comments and our responses regarding § 92.101 of subpart B are set forth below.

Comment: A few commenters recommended that OCR add the words “or deterred” to the general prohibition of discrimination, so that it would read as follows: “Except as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded or deterred from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies.”

Response: We believe the regulatory text, as it is currently written, conveys the intent to prohibit discriminatory deterrence from participation in a health program or activity. As OCR noted in the preamble to the proposed rule, paragraph (a)(1) of § 92.101 prohibits discrimination on the grounds prohibited under Title VI, Title IX, the Age Act, and Section 504 in any health program or activity to which this part applies. It is well established under these and other civil rights law that deterrence on the basis of a prohibited criterion is a form of discrimination. Similarly, discrimination on the basis of perceived race, color, national origin, sex, age, or disability is prohibited discrimination under the final rule, as it is under the authorities referenced in Section 1557.

Comment: One commenter asked for clarification that, when scientific evidence supports differential treatment to ensure safe, high-quality care, such treatment would not be considered discriminatory. This commenter pointed out that the risks and benefits of treatments may differ due to characteristics such as age, gender, physical stature, and genetics. For example, based on the best available science, experts have judged that, for men and younger women, absent a known family history, the risks associated with radiation exposure from routine mammograms outweigh the benefits. Thus, practice guidelines suggest not administering screening mammograms to women under a certain age or to men.

Response: Scientific or medical reasons can justify distinctions based on the grounds enumerated in Section 1557. We affirm this understanding of the final rule and believe that the

regulatory text encompasses that approach.

Comment: A few commenters asked that OCR prohibit discrimination in health programs or activities on the basis of “health status, claims experience, medical history, or genetic information” in addition to race, color, national origin, sex, age, and disability.

Response: This rule implements Section 1557 of the ACA, which prohibits discrimination on the bases of race, color, national origin, sex, age, and disability. Accordingly, the commenters’ request is beyond the scope of this rule. However, OCR recognizes that discrimination based on health status, claims experience, medical history, or genetic information can, depending on the facts, have a disparate impact that results in discrimination on a basis prohibited by Section 1557 and will process complaints alleging such discrimination accordingly. In addition, such discrimination also may violate other laws, such as other provisions of the ACA or the Genetic Information Nondiscrimination Act of 2008.¹²³

Comment: Many commenters disagreed with the approach taken in the proposed rule to exclude discrimination in employment in areas other than employee health benefits. Commenters stated that the text of Section 1557 does not exclude employment discrimination; that Section 1557 protects “individuals,” similar to Title IX’s protection of “person[s];” and that Title IX has been interpreted to protect not just students but employees of educational institutions. They also noted that Section 504 covers employment without exception and that Title VI covers employment discrimination when it affects beneficiaries of the covered program.¹²⁴

Response: For the reasons stated in the preamble to the proposed rule, OCR declines to interpret Section 1557 to grant itself jurisdiction (outside the context of employee health benefit plans under circumstances set out in § 92.208) over claims of employment discrimination brought by employees against their employers that are covered entities. In holding that both Title IX and Section 504 broadly prohibit discrimination in employment, the Supreme Court relied heavily on the legislative history and underlying purpose of these statutes.¹²⁵ By contrast,

there is no indication that broadly prohibiting employment discrimination was a chief purpose of Section 1557, which is focused on discrimination against participants in health programs and activities. To the extent that employees who are subject to discrimination are employed by entities that are covered under other employment discrimination laws, their complaints can be brought under those other laws. And as to employees of small employers, we do not believe that Congress in Section 1557 intended to alter, across the board, the longstanding exclusion of small employers from most employment discrimination laws. That said, nothing in this rule is intended to alter the established principles underlying the unlimited coverage of employment discrimination under both Title IX and Section 504, and OCR will process such claims brought under these statutes under its longstanding procedures.¹²⁶

Comment: Some commenters asked that OCR clarify that Section 1557’s prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability includes intersectional discrimination that might affect persons who are part of multiple protected classes. For example, discrimination against an African-American woman could be discrimination on the basis of both race and sex.

Response: OCR is clarifying here that Section 1557’s prohibition of discrimination reaches intersectional discrimination. We believe that the regulatory text encompasses this approach.

Comment: Commenters noted that various forms of harassment in health care can discourage individuals from seeking care and suggested that OCR include a separate provision that explicitly prohibits all forms of harassment based on protected characteristics, including sexual harassment and other forms of sex-based harassment.

Response: OCR recognizes that various forms of harassment can impede an individual’s ability to participate in

¹²⁶ Moreover, nothing in this rule is intended to affect OCR’s ability to address discrimination against patients on a prohibited basis, even where that discrimination is effectuated through actions against a covered entity’s employee. If, for example, a medical practice that receives Federal financial assistance fired a Hispanic doctor because the practice no longer wished to serve the doctor’s predominantly Hispanic, limited English proficient patients, OCR could pursue relief on behalf of affected patients to ensure that their access to the practice was not discriminatorily denied. Cf. 45 CFR 80.3(c)(3) (Title VI applies where discrimination in employment tends to exclude individuals, on the basis of race, color, or national origin, from participation in a covered program).

¹²³ *Supra* note 3.

¹²⁴ See *North Haven Bd. of Educ. v. Bell*, 456 U.S. 512 (1982).

¹²⁵ *Id.* at 522–30; *Consolidated Rail v. Darrone*, 465 U.S. 624, 626 (1984).

or benefit from a health program or activity and can thus constitute unlawful discrimination under Section 1557 and this part. Under Title IX, harassing conduct creates a hostile environment if the conduct is sufficiently serious to interfere with or limit an individual's ability to participate in or benefit from a program.¹²⁷ For example, a provider's persistent and intentional refusal to use a transgender individual's preferred name and pronoun and insistence on using those corresponding to the individual's sex assigned at birth constitutes illegal sex discrimination if such conduct is sufficiently serious to create a hostile environment. Similarly, a provider using derogatory language because an individual is an unmarried sexually active or pregnant woman constitutes illegal sex-based harassment if such conduct is sufficiently serious to create a hostile environment. Consistent with the well-established interpretation of existing civil rights laws, OCR interprets the final rule to prohibit all forms of unlawful harassment based on a protected characteristic. Because it has been long-established that harassment is a form of prohibited discrimination under each of the laws cited in Section 1557 and this part, OCR does not believe a separate harassment provision is necessary and therefore declines to revise the proposed rule to include one.

Comment: Many commenters recommended that OCR add regulation text stating that the Tri-Agency Guidance¹²⁸ imposes legally enforceable obligations on entities covered by Section 1557 and that OCR has direct authority to enforce the Tri-Agency Guidance as well as the statutory and regulatory provisions therein articulated.¹²⁹ The Tri-Agency Guidance describes how States can

structure their application and enrollment processes in compliance with Title VI and program authorities to ensure that State agencies do not administer federally assisted public benefit programs in a manner that delays or denies services to eligible individuals, including children, living in mixed-immigration status households.

Commenters asked for such regulatory language based on concerns that some covered entities administer their programs in a manner that discriminates based on national origin by delaying or denying access to public benefits based on practices such as: Erecting onerous documentation requirements; denying eligible applicants the opportunity to prove eligible income, identity, citizenship status, or immigration status; or making generalized assumptions about applicants' eligibility based on the actual or perceived immigration status or national origin of any family member.¹³⁰ Commenters also expressed concern that some covered entities fail to understand the eligibility differences between various immigrant visa statuses and length of residency requirements, fail to distinguish between applicants and non-applicants in requests for Social Security numbers (SSNs), or require the disclosure of SSNs or immigration status without first explaining the use or confidentiality of this information.

Response: OCR appreciates hearing from commenters on this important issue. However, we decline to explicitly reference, in regulation, the Tri-Agency Guidance and the authorities therein articulated for two main reasons. First, it is beyond the scope of this final rule to address program authorities over which OCR does not have enforcement authority.

Second, regulatory modifications to the proposed rule are unnecessary to allow OCR to address a covered entity's policy or practice, such as requiring the disclosure of SSNs or certain citizenship or immigration status information, that raises compliance concerns under Section 1557's prohibition of national origin discrimination. OCR addresses

such issues under Title VI.¹³¹ We similarly have authority to address such issues under Section 1557 and this part when, for example, an individual's complaint alleges that a covered entity has implemented a facially-neutral policy, such as requiring the disclosure of immigration status from applicants and non-applicants, that has a disparate impact on individuals of a particular national origin group.

Thus, to the extent that the Tri-Agency Guidance identifies situations that may raise Title VI compliance concerns and offers best practices for resolving those concerns, this information is equally applicable to health programs and activities covered under Section 1557 as it is to the health and human service programs addressed in the Tri-Agency Guidance. The Department continues to adhere to the principles set forth in the Tri-Agency Guidance in the implementation of the Department's programs¹³² and through OCR's enforcement of Title VI. OCR intends to apply these principles in our enforcement of Section 1557 and this part and will continue to accept complaints alleging that covered entities' actions deter eligible individuals from applying for benefits offered by health programs and activities on the basis of their national origin. Section 1557 and this part, however, do not alter programmatic laws and regulations that restrict eligibility for particular health programs to persons of certain immigration or

¹³¹ See HHS OCR VRA with AZ Agencies, *supra* note 53, (resolving cognizable complaints of national origin discrimination under Title VI following implementation of an Arizona State law requiring State employees, in the administration of public benefits programs, to report "discovered violations of federal immigration law" to U.S. Immigrations and Customs Enforcement).

¹³² See, e.g., 77 FR 18310, 18355 (Mar. 27, 2012) (applying the principles of the Tri-Agency Guidance to MarketplaceSM regulations on the health insurance application process); U.S. Dep't of Health & Human Servs., Office of Community Servs., Admin. on Children & Families, HHS Guidance on the Use of Social Security Numbers and Citizenship Status Verification for Assistance by LIHEAP Grantees' Programs, A6 (2014), <http://www.acf.hhs.gov/programs/ocs/resource/liheap-imm-hhs-guidance-on-the-use-of-social-security-numbers-ssns-and-citizenship-status-verification> (strongly encouraging LIHEAP Grantees to structure their eligibility processes to avoid the delay or denial of benefits to eligible persons in mixed-immigration status households); U.S. Dep't of Health & Human Servs., Admin. on Children & Families, Office of Child Care, Clarifying Policy Regarding Limits On The Use Of Social Security Numbers Under the Child Care and Development Fund and the Privacy Act Of 1974, Program Instr. No. ACYF-PI-CC-00-04 (2000), <http://www.acf.hhs.gov/programs/occ/law/guidance/current/pi0004/pi0004.htm> (requiring States to make clear that the provision of a SSN is voluntary and child care benefits will not be denied or withheld for failure to provide a SSN).

¹²⁷ See, e.g., U.S. Dep't of Educ., Office for Civil Rights, Questions and Answers on Title IX and Sexual Violence (2014) at A-2, available at <http://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf>.

¹²⁸ U.S. Dep't of Health & Human Servs. and U.S. Dep't of Agriculture, Policy Guidance Regarding Inquiries into Citizenship, Immigration Status and Social Security Numbers in State Applications for Medicaid, State Children's Health Insurance Program (CHIP), Temporary Assistance for Needy Families (TANF), and Food Stamp Benefits (2000) [hereinafter Tri-Agency Guidance], <http://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/tri-agency/index.html> (describing how States can structure their facially-neutral policies and practices to enroll eligible children and families of all national origins to reduce and eliminate access barriers).

¹²⁹ In addition to Title VI, the Tri-Agency Guidance addresses the Privacy Act of 1974 and program authorities authorizing and implementing Medicaid, CHIP, Temporary Assistance for Needy Families, and the Food Stamp Program. *Id.* at 1-2, Q2.

¹³⁰ The Tri-Agency Guidance addresses the circumstances under which a State may not deny benefits when a non-applicant applying on behalf of a child, or a non-applicant household member, does not provide information regarding his or her citizenship status, immigration status or a Social Security number. The Guidance recommends that public benefits applications allow non-applicants to declare early in the process whether they are seeking benefits only on behalf of an eligible child or family member so that further inquiry is limited to factors necessary for determining the child's or family member's eligibility. *Id.* at 206, Q3-Q7.

citizenship statuses, and thus allow covered entities to make requests for that information when required by such authorities.¹³³

Comment: A few commenters recommended that HHS clarify its longstanding position that the regulations implementing Section 504 require health care entities with fewer than 15 employees to provide auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question. These commenters pointed out that while 45 CFR 84.52(d)(1) requires the provision of auxiliary aids only by covered entities with 15 or more employees, 45 CFR 84.52(d)(2) provides that the Director may require recipients with fewer than 15 employees to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services. The commenters recognized that in 2000, HHS issued a notice in the **Federal Register** announcing that the Director had decided to require recipients with fewer than 15 employees to provide appropriate auxiliary aids pursuant to 42 CFR 84.52(d)(2).¹³⁴ However, the commenters also asserted that some judicial decisions have questioned whether the Director's notice constitutes a binding legislative rule or merely a policy statement by HHS.¹³⁵ Accordingly, these commenters were concerned that the proposed rule's incorporation of 45 CFR 84.52(d) might not be clear enough to also incorporate the Director's notice that health care entities with fewer than 15 employees must provide auxiliary aids and services on the same basis as health care entities with 15 or more employees.

Response: To ensure clarity as to our intent, we have revised the language in § 92.101(b)(2)(i) to delete the reference to 45 CFR 84.52(d) and have added new language to that section requiring covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and

services to persons with impaired sensory, manual, or speaking skills where necessary to afford such persons an equal opportunity to benefit from the service in question.

As explained in the Director's original notice adopting this policy, OCR believes that Section 504's auxiliary aids and services requirement should be applied to covered entities with fewer than 15 employees in the interest of uniformity and consistent administration of law. Under Title III of the ADA, privately operated public accommodations are obligated to provide appropriate auxiliary aids and services, regardless of their size, where necessary to ensure effective communication with individuals with disabilities, unless they can demonstrate that taking such steps would fundamentally alter the nature of their program, services or activities, or would result in undue financial and administrative burdens.¹³⁶ OCR's decision to require all entities, regardless of size, to provide auxiliary aids and services under Section 1557 and this part thus furthers consistency among disability discrimination laws; importantly, it also furthers the ACA's goal of improving access to health coverage and health care because requiring all entities to provide auxiliary aids and services will result in enhanced services for people with disabilities. Moreover, because this requirement has been OCR's policy for more than a decade, covered entities are familiar with the obligations it imposes.

Comment: A few commenters asked that OCR add language to the rule declaring that medical treatment for individuals with disabilities must be as effective as treatment for individuals without disabilities.

Response: At § 92.101(b)(2)(i), the final rule incorporates 45 CFR 84.4(b)(1)(iii) of the Section 504 implementing regulation, which states that recipients may not provide qualified individuals with disabilities “with an aid, benefit, or service that is not as effective as that provided to others. . . .” Such benefits include medical treatment, though recipients cannot, and are not required under the rule to, ensure equally effective outcomes.

Comment: A number of commenters urged that OCR make clear that, consistent with the requirements of Title II of the ADA and Section 504,¹³⁷

disability-based discrimination under Section 1557 encompasses the needless segregation of individuals with disabilities. They pointed, in particular, to the need to make clear that covered entities must make coverage and reimbursement decisions that support serving individuals with disabilities in integrated settings unless doing so would fundamentally alter the entities' service systems, citing to the HHS Guidance on Medicaid Managed Care.¹³⁸

Response: We agree that since Section 1557 explicitly incorporates Section 504's prohibitions against disability-based discrimination, it therefore encompasses a ban on the unnecessary segregation of individuals with disabilities. As such, and as required by Title II of the ADA and Section 504 and interpreted in *Olmstead v. L.C.*¹³⁹ and its progeny, public entities (State and local governments) must administer services to individuals with disabilities in the most integrated setting appropriate to their needs unless doing so is a fundamental alteration of the public entity's service delivery system. The “most integrated setting” mandate applies to the full spectrum of the public entity's service delivery system, including coverage and reimbursement decisions, when the entity “(1) directly or indirectly operates facilities and or/programs that segregate individuals with disabilities; (2) finances the segregation of individuals with disabilities in private facilities; and/or (3) through its planning, service system design, funding choices, or service implementation practices, promotes or relies upon the segregation of individuals with disabilities in private facilities or programs.”¹⁴⁰ OCR will continue its ongoing *Olmstead* enforcement efforts under Section 504 and Title II of the ADA, as well as Section 1557 and this part, where appropriate.

Comment: Several commenters recommended that OCR specify that age-related distinctions are prohibited, apart from exclusions in the Age Act for (1) age distinctions contained in a

¹³³ See, e.g., 45 CFR 155.305(f)(6) (in some cases, a MarketplaceSM must require the SSN of an individual who is not requesting coverage for himself or herself, but whose SSN could be used to verify eligibility information for a household member who is requesting MarketplaceSM coverage and financial assistance, such as a child).

¹³⁴ See U.S. Dep't of Health & Human Servs., Office for Civil Rights; Section 504 of the Rehabilitation Act of 1973; Notice of Exercise of Authority Under 45 CFR 84.52(d)(2) Regarding Recipients With Fewer Than Fifteen Employees, 65 FR 79368 (Dec. 19, 2000).

¹³⁵ See, e.g., *Columbia v. Gregory*, Civ. No. 08–cv–98, 2008 WL 4192437, *4 (D.N.H. Sep. 9, 2008).

¹³⁶ See 42 U.S.C. 12182(b)(2)(A)(iii).

¹³⁷ See 28 CFR 35.130(b)(7) (requiring public entities to administer services to individuals with disabilities in the most integrated setting appropriate to their needs); 45 CFR 84.4(b)(2); *Olmstead v. L.C.*, 527 U.S. 581 (1999).

¹³⁸ U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Services, Guidance to States Using 1115 Demonstrations or 1915(b) Waivers for Managed Long Term Services and Supports Programs 3 (May 20, 2013), <https://www.medicare.gov/medicaid-chip-program-information/by-topics/delivery-systems/downloads/1115-and-1915b-mltss-guidance.pdf>.

¹³⁹ 527 U.S. 581 (1999).

¹⁴⁰ U.S. Dep't of Justice, Statement of the Department of Justice on Enforcement of the Integration Mandate of Title II of the Americans with Disabilities Act and *Olmstead v. L.C.*, (June 21, 2011), http://www.ada.gov/olmstead/q&a_olmstead.htm.

Federal, State or local statute or ordinance that provide benefits based on age, establish criteria for participation in age-related terms, or describe intended beneficiaries to target groups in age-related terms, and (2) actions that reasonably take into account age as a factor necessary to the normal operation or the achievement of any statutory objective of such program or activity. Under these comments, for example, a decision to limit coverage of a service to individuals in a particular age range, even though that service is also effective for individuals of other ages, would violate Section 1557 if the age limitation is not based on a statute or ordinance and is not necessary for the normal operation or achievement of the goals of the service.

Response: OCR declines to adopt the standard recommended by the commenters. As noted elsewhere, the rule permits actions based on age to overcome the effects of conditions that resulted in limited participation in the covered entity's health program or activity based on age.¹⁴¹ We also note that other provisions of the rule incorporate provisions in the regulation implementing the Age Act that permit age distinctions in HHS regulations and a recipient's provision of special benefits to the elderly or children.¹⁴²

Comment: A few commenters asked that OCR clarify that State mandates that have age limits are exempt and that States are allowed to create new State mandates that have age distinctions if that is clinically appropriate.

Response: As reflected in the provision of the final rule at § 92.2(b)(1), age distinctions contained in Federal, State, or local statutes or ordinances adopted by an elected, general purpose legislative body are not covered by the final rule. States may adopt new laws that contain age distinctions; those distinctions would not violate the final rule.¹⁴³

Comment: One commenter asked us to clarify the application of Section 1557 with respect to age rating in health insurance plans and related employer contributions.

Response: As we noted above, OCR is incorporating in the final rule the exclusions found in the Age Act, such that the provisions of the proposed rule would not apply to any age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose

legislative body which provides any benefits or assistance to persons based on age, establishes criteria for participation in age-related terms, or describes intended beneficiaries to target groups in age-related terms.¹⁴⁴ For instance, age rating in premium rates within a 3:1 ratio in MarketplaceSM plans would not violate Section 1557 because it is permitted under the ACA.¹⁴⁵ Further, this rule would not prohibit a covered entity from establishing and applying, or offering a plan on a MarketplaceSM that establishes or applies, in a nondiscriminatory manner, neutral rules related to employer contribution amounts, such as contributing a fixed percentage or dollar amount of each employee's premium or placing a cap on the total amount of employer contributions, even though the dollar amount of the contribution or the employee's share of the premium may be smaller or greater for some employees than for others based on the permissible age rating of the employee's premium.

Comment: One commenter recommended that OCR clarify that in order to operate in a nondiscriminatory manner, issuers must ensure that their plans do not impose arbitrary age, visit, or coverage limits. This commenter pointed out that children often need more frequent preventive and supportive services than adults, including immunizations, developmental assessments and screenings, and nutritional counseling, to enable them to maintain or improve their health into adulthood. Furthermore, children with special health needs may need additional services, such as speech or physical therapy, on a more frequent basis than adults to enable them to develop specific skills or meet their developmental potential. Similarly, children will also require replacement of durable medical equipment or devices on a much more frequent schedule than is provided in an adult benefit package.

Response: OCR agrees that arbitrary age, visit, or coverage limitations could constitute discrimination, including discrimination based on age, in certain cases, for example where consideration of age is not necessary to the normal operation of a health program. In addition, as noted above, where differential treatment is justified by scientific or medical evidence, such treatment will not be considered

discriminatory. The general prohibition of discrimination in the rule applies to these issues.

Comment: Commenters noted that due to the educational context for which they were created, Title IX regulations do not reach the full breadth of discriminatory actions on the basis of sex that are prohibited by Section 1557; these commenters recommended that the final regulation incorporate prohibitions from Title VI, Section 504, and the Age Act to more fully address discrimination on the basis of sex in health programs and activities. In addition, commenters stated that the final rule should make clear that in the absence of a finding of discrimination, a covered entity may take affirmative action to overcome the effects of conditions which resulted in limited participation by persons on the basis of sex.

Response: OCR appreciates the concern raised by the commenters that, due to the fact that Title IX applies only to educational programs, the full range of specific discriminatory actions prohibited under other laws is not explicitly included in Title IX's regulations. OCR has revised the final regulation to incorporate additional language in § 92.101(b)(3) to help clarify the full breadth of discriminatory actions that can constitute sex discrimination under Section 1557. Additionally, both the proposed and the final rule make clear in § 92.6 (Remedial Action and Voluntary Action) that covered entities are permitted, but not required, to take voluntary action in the absence of a finding of discrimination to overcome the effects of conditions that result or resulted in limited participation by persons based on any prohibited ground covered under the regulation.

Comment: Several commenters noted that although sex-specific programs may be clinically necessary in some instances, for example, in clinical trials that aim to determine whether sex differences exist in the manifestation or recommended treatment of certain diseases, the Department should clarify that sex-specific programs—*i.e.*, those in which participation is limited to members of one sex only—are permissible only when they are narrowly tailored and necessary to accomplish an essential health purpose.

Response: OCR agrees with commenters that sex-specific programs (programs limited exclusively to one sex) should be permitted only under limited circumstances. OCR believes that the constitutional standard established by the Supreme Court in

¹⁴¹ See § 92.101(c).

¹⁴² See § 92.101(c) (incorporating 45 CFR 91.17).

¹⁴³ We note that age limits may violate CMS regulations under the ACA and covered entities are responsible for ensuring compliance with all applicable CMS regulations and other Federal laws.

¹⁴⁴ See 42 U.S.C. 6103(b).

¹⁴⁵ 42 U.S.C. 300gg(a)(1)(A)(iii). See also 45 CFR 147.102.

*United States v. Virginia*¹⁴⁶ provides the most appropriate level of protection and thus has chosen to adapt this standard for application in evaluating the lawfulness of sex-specific health programs or activities under Section 1557 and this part. In *Virginia*, the Court stated that a governmental entity attempting to justify a sex-specific program must demonstrate an “exceedingly persuasive justification” for a sex-based classification in accordance with the U.S. Constitution’s Equal Protection Clause.¹⁴⁷ As the Court explained, this means that the governmental entity must show “at least that the [challenged] classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives.”¹⁴⁸ In *Virginia*, which challenged Virginia Military Institute’s male-only admissions policy, the Court found that the governmental entity had fallen “far short of establishing the exceedingly persuasive justification” necessary to sustain a sex-based classification.¹⁴⁹ The Court made clear that proffered justifications cannot rely on overbroad generalizations and cannot be hypothesized or invented post hoc in response to litigation.¹⁵⁰

Under this demanding standard, as adapted in this rule, a sex-specific health program or activity classification is unlawful unless the covered entity can show an exceedingly persuasive justification for it, that is, that the sex-based classification is substantially related to the achievement of an important health-related or scientific objective. In evaluating a complaint of discrimination challenging a covered entity’s sex-specific health program or activity, OCR may consider a variety of factors relevant to the particular program or activity. In all cases, however, OCR will expect a covered entity to supply objective evidence, and empirical data if available, to justify the need to restrict participation in the program to only one sex. In no case will OCR accept a justification that relies on overly broad generalizations about the sexes.

Under this standard, OCR anticipates that most health researchers will be able to justify sex-specific clinical trials, such as those that test treatments for sex-specific conditions or that evaluate differences in responses to treatment regimens among the sexes, based upon

the scientific purposes of the study. Where there is no clinical or scientific rationale for making a program sex-specific, by contrast, a covered entity that offers such a program would need to demonstrate, through such means as research literature, empirical data, accepted professional standards, and/or facts specific to participants in the program, that maintaining the sex segregation of the program is necessary for the program to achieve its purpose. Overly broad generalizations would not be sufficient.

No commenters asked OCR to adopt the sex-specific standards authorized in Title IX or the Department of Education’s Title IX regulations. OCR has chosen to apply an adapted constitutional standard under Section 1557 rather than the standard authorized in Title IX and the Department of Education’s Title IX regulations because, as noted in the proposed rule, and by several commenters, the single-sex educational exceptions found in Title IX and the Department of Education’s Title IX regulations—such as exceptions for some single-sex education programs (e.g., contact sports in physical education classes; classes on human sexuality; and choruses) when certain requirements are met—do not readily apply in a context grounded in health care.

In addition, we note that OCR’s adaptation of the constitutional standard as the standard to be applied to sex-specific health programs or activities under Section 1557 is consistent with the constitutional standard that already applies to sex-specific public health programs and activities, which are covered entities under this rule if they receive Federal financial assistance. OCR has adapted the standard to use the term “important health-related or scientific objective,” in recognition of the fact that the rule’s provision on sex-specific programs or activities applies to both private and public covered entities in the context of health programs and activities. The same Section 1557 nondiscrimination standards, including this adapted standard, apply to health programs or activities subject to this rule whether public or private covered entities operate them.

Finally, as we initially noted in the proposed rule, we do not intend to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex. OCR recognizes that under some existing Federal, State and local laws, rules or regulations, certain types of sex-specific facilities such as

restrooms may be permitted. The approach taken by OCR is consistent with the long standing approach taken to these types of facilities.

However as previously stated in the discussion of the definition of “on the basis of sex” in § 92.4, even where it is permissible to make sex-based distinctions, individuals may not be excluded from health programs and activities for which they are otherwise eligible based on their gender identity.¹⁵¹ Courts have rejected claims that any legal right to privacy is violated and that one person suffers any cognizable harm simply by permitting another person access to a sex-specific program or facility which corresponds to their gender identity.¹⁵²

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.101 with the following modifications:

We have re-designated § 92.101(b)(1) as § 92.101(b)(1)(i), and added a new section § 92.101(b)(1)(ii), which prohibits aiding or perpetuating discrimination against an individual by providing significant assistance to an entity or person that discriminates on the basis of race, color, or national origin against beneficiaries of the covered entity’s health program or activity. Similarly, we have re-designated § 92.101(b)(4) as § 92.101(b)(4)(i), and added a new section § 92.101(b)(4)(ii), which prohibits aiding or perpetuating discrimination against an individual by providing significant assistance to an entity or person that discriminates on the basis of age against health program or activity beneficiaries. These provisions complement similar provisions incorporated in the final rule with respect to disability and sex discrimination and are included to ensure that we are providing the same protections from race, color, national origin, and age discrimination as are provided with respect to sex and disability discrimination.

In addition, we have changed the language in § 92.101(b)(2)(i) to exclude reference to 45 CFR 84.52(d). We are re-designating the existing regulation text at § 92.202 as § 92.202(a), and adding a

¹⁴⁶ 518 U.S. 515 (1996).

¹⁴⁷ *Id.* at 531–32.

¹⁴⁸ *Id.* at 532–33 (internal citations omitted).

¹⁴⁹ *Id.* at 533–34.

¹⁵⁰ *Id.* at 533.

¹⁵¹ See *Lusardi v. McHugh*, U.S. Equal Employment Opportunity Comm’n Appeal No. 0120133395, Agency No. ARREDSTON11SEP05574, 2015 WL 1607756 (April 1, 2015) (finding Agency’s denial of Complainant’s access to the common women’s restroom on account of her gender identity violated Title VII), <http://www.eeoc.gov/decisions/0120133395.txt>.

¹⁵² See, e.g., *Crosby*, 763 F. Supp. 666; cf. *Cruzan*, 294 F.3d 981.

new subsection, § 92.202(b) that requires covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

We have re-designated the existing regulation text at § 92.101(b)(3) as § 92.101(b)(3)(i). We have added new subsections, § 92.101(b)(3)(ii) and § 92.101(b)(3)(iii) to clarify the full breadth of discriminatory actions prohibited by Section 1557 on the basis of sex. Last, we have added a new subsection, § 92.101(b)(3)(iv) to clarify when covered entities may provide a sex-specific health program or activity.

Subpart C—Specific Applications to Health Programs and Activities

Section 1557 is unique among Federal civil rights laws in that it specifically addresses discrimination in health programs and activities. To provide additional specificity regarding nondiscrimination requirements in this setting, Subpart C builds upon pre-existing civil rights regulations referenced in Subpart B.

Meaningful Access for Individuals With Limited English Proficiency (§ 92.201)

Overview of § 92.201

In § 92.201, OCR proposed to effectuate Section 1557's prohibition on national origin discrimination as it affects individuals with limited English proficiency in health programs and activities of covered entities.

We explained that for individuals with limited English proficiency, lack of proficiency in English—and the use of non-English languages—is a direct outgrowth of, and is integrally tied to, their national origins.¹⁵³ It is well-established under Title VI and its implementing regulation that a prohibition on national origin discrimination requires covered entities to take reasonable steps to provide meaningful access to individuals with limited English proficiency.¹⁵⁴ The U.S.

Supreme Court has held that the provision of language assistance services is essential to ensure the equality of opportunity promised by nondiscrimination laws.¹⁵⁵ As we stated in the Department's 2000 LEP Policy Guidance:

The key to providing meaningful access for LEP persons is to ensure that the recipient/covered entity and LEP person can communicate effectively. The steps taken by a covered entity must ensure that the LEP person is given adequate information, is able to understand the services and benefits available, and is able to receive those for which he or she is eligible. The covered entity must also ensure that the LEP person can effectively communicate the relevant circumstances of his or her situation to the service provider.¹⁵⁶

General Requirements § 92.201(a), (b) and (c)

In § 92.201(a), we proposed to adopt the well-established principle that covered entities must take reasonable steps to provide meaningful access to health programs and activities for all individuals with limited English proficiency whom the covered entities serve or encounter.¹⁵⁷ We provided that, consistent with our longstanding enforcement of Title VI, we intended the general obligation in paragraph (a) to be a context-specific standard that the Director considers in light of the particular facts.¹⁵⁸

Human Servs., Office for Civil Rights, Policy Guidance, Title VI Prohibition against National Origin Discrimination As It Affects Persons with Limited English Proficiency, 65 FR 52762, 52765 (August 30, 2000) (“The most important step in meeting this [meaningful access] obligation is for recipients of Federal financial assistance such as grants, contracts, and subcontracts to provide the language assistance necessary to ensure such access, at no cost to the LEP person.”). See also Exec. Order No. 13166, *Improving Access to Services for Persons with Limited English Proficiency*, 65 FR 50121 (Aug. 11, 2000) (requiring each Federal Department to improve access to Federally assisted programs and activities by persons with limited English proficiency and to implement a system by which individuals with limited English proficiency can meaningfully access the Departments' Federally conducted programs and activities).

¹⁵⁵ 80 FR at 54182 (citing *Lau*, 414 U.S. at 566) (reasoning that a federally funded educational program's failure to take affirmative steps to rectify the language deficiency of limited English proficient students of Chinese ancestry denies them a meaningful opportunity to participate in the educational program on the basis of their national origin).

¹⁵⁶ 65 FR at 52765.

¹⁵⁷ The Department's LEP Guidance provides an in-depth explanation of Title VI's prohibition against national origin discrimination as it affects limited English proficient populations and how recipients can determine what steps are reasonable to provide all individuals with limited English proficiency meaningful access. HHS LEP Guidance, *supra* note 49.

¹⁵⁸ Under Title VI, OCR investigates each complaint and conducts its compliance reviews on

We stated that the proposed standard balances two core principles critical in effectuating Section 1557's prohibition of national origin discrimination. First, the Department must “ensure that [health programs and activities] aimed at the American public do not leave some behind simply because they face challenges communicating in English.”¹⁵⁹ We noted that provider-patient communication is essential to the concept of patient centeredness, which is a core component of quality health care and has been shown to improve patients' health and health care.¹⁶⁰ Second, we stated that the level, type and manner of language assistance services required under paragraph (a) should be assessed based on the relevant facts, which may include the operations and capacity of the covered entity.

For these reasons, proposed paragraph (b) identified how the Director will evaluate whether a covered entity has met the requirement in paragraph (a).¹⁶¹ In paragraph (b)(1), we proposed to require the Director to consider, and give substantial weight to, the nature and importance of the health program or activity, including the particular communication at issue. In paragraph (b)(2), we proposed to require the Director to take other relevant factors into account and identified some of those that might be relevant.

In paragraphs (b)(2)(i) and (ii), OCR proposed to identify the length, complexity, and context of the

a case-by-case basis and tailors each case resolution to the particular facts of each case. For highlights of OCR's Title VI enforcement specific to the prohibition of national origin discrimination as it affects individuals with limited English proficiency, see *Enforcement Success Stories Involving Individuals with Limited English Proficiency*, U.S. Dep't of Health & Human Servs., Office for Civil Rights, <http://www.hhs.gov/ocr/civilrights/activities/examples/LEP/index.html> (last visited May 4, 2016).

¹⁵⁹ 80 FR 54172, 54183 (quoting HHS LEP Guidance, *supra* note 49, 68 FR at 47312).

¹⁶⁰ *Id.* (citing U.S. Dep't of Health & Human Servs., Agency for Health Care Research & Quality, Chapter 6, Patient Centeredness, National Healthcare Quality Report (2013), <http://www.ahrq.gov/research/findings/nhqrdr/nhqr13/chap6.html>). Person-centered and family centered care is one of the six priorities of the National Quality Strategy. Dep't. of Health & Human Servs., Agency for Health Care Research & Quality, 2014 National Healthcare Quality and Disparities Report, Person- and Family-Centered Care Chartbook, AHRQ Pub. No. 15-0007-14, at 3 (May 2015), <http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/2014chartbooks/personcentered/personcenteredcare-chartbook.pdf>.

¹⁶¹ *Id.* at 54183 n.53 (stating that the Department's LEP Guidance takes a similar approach by identifying the factors that OCR will consider, in determining the extent of a recipient's obligations to individuals with limited English proficiency). See HHS LEP Guidance, *supra* note 49, 68 FR at 47314-16.

¹⁵³ See, e.g., 80 FR at 54182.

¹⁵⁴ See, e.g., *Lau v. Nichols*, 414 U.S. 563, 566 (1974) (interpreting Title VI and its implementing regulations to require a school district with students with limited English proficiency of Chinese origin to take affirmative steps to provide the students with a meaningful opportunity to participate in Federally funded educational programs); HHS LEP Guidance, *supra* note 49, 68 FR at 47313 (“[T]he failure of a recipient of [F]ederal financial assistance from HHS to take reasonable steps to provide LEP persons with [a] meaningful opportunity to participate in HHS funded programs may constitute a violation of Title VI and HHS's implementing regulations”); U.S. Dep't of Health &

communication as potentially relevant factors in a particular case. We noted that where a communication is particularly long or complex, a covered entity might be required to provide a means for an individual with limited English proficiency to be able to refer back to the information communicated by providing, for instance, a document written in the individual's primary language or an audio file of the information conveyed orally.

In paragraph (b)(2)(iii), we provided that the prevalence of the primary language in which the individual with limited English proficiency communicates, among those eligible to be served or likely to be encountered by the health program or activity, might also be relevant.

In paragraphs (iv) and (v) of proposed § 92.201(b)(2)—the final illustrative factors listed—we noted that the resources available to the covered entity and the costs of language assistance services might also be relevant in a particular case.

In proposed paragraph (c), we clarified that language assistance services required under paragraph (a) must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency.¹⁶²

Specific Requirements for Interpreter Services and Restricted Use of Certain Persons to Interpret or Facilitate Communication § 92.201(d) and (e)

In paragraphs (d) and (e), OCR proposed to codify standards described in the Department's LEP Guidance regarding qualified interpreters for individuals with limited English proficiency and the use of family members or friends as interpreters or to facilitate communication.¹⁶³ These proposed standards account for issues of competency, confidentiality, privacy, and conflict of interest that arise as a result of relying on informal (or ad hoc) interpreters. We noted that paragraphs (d) and (e) are consistent with oral interpretation standards that OCR has advanced through its resolution of Title VI cases and compliance reviews.¹⁶⁴

¹⁶² 80 FR at 54183 (citing HHS LEP Guidance, *supra* note 49, 68 FR at 47318, 47323 (with respect to privacy), 47316–17, 47322 (with respect to timeliness), and 47318–19, 47320, 47322 (with respect to services free of charge)).

¹⁶³ *Id.* at 54183–84 (citing HHS LEP Guidance, *supra* note 49, 68 FR at 47317–18, 47323).

¹⁶⁴ See, e.g., HHS OCR VRA with Mee Memorial Hosp., *supra* note 82, at pt. II.J (defining qualified interpreter); HHS OCR VRA with Montgomery County DSS, *supra* note 82, at pts. II.E (defining qualifications of an "interpreter"), IV.H (requiring

Specifically, in paragraph (d), OCR proposed to address standards applicable to oral interpretation. We provided that when a covered entity is required by paragraph (a) to provide oral interpretation as a reasonable step to provide meaningful access to an individual with limited English proficiency, the covered entity must offer that individual a qualified interpreter.

In paragraph (e), we proposed restrictions on the use of certain persons to interpret or facilitate communication for an individual with limited English proficiency. We proposed that paragraph (e) apply in addition to, and regardless of, the appropriate level, type or manner of language assistance services a covered entity is required to provide. In paragraph (e)(1), we proposed to prohibit a covered entity from requiring an individual with limited English proficiency to provide his or her own interpreter. However, in paragraphs (e)(2)(i) and (ii), we proposed to identify narrow and finite situations in which a covered entity may rely on an adult accompanying an individual with limited English proficiency to interpret. In paragraph (e)(3), we proposed to prohibit a covered entity from relying on a minor child to interpret or facilitate communication and identified an exception to this prohibition that is narrower in scope than the exception identified in (e)(2)(i) and (ii).

We explained that in lieu of the approach we proposed in paragraphs (d) and (e), we considered proposing that all covered entities have the capacity to provide, in their health programs or activities, qualified interpreters for individuals with limited English proficiency through telephonic oral interpretation services available in at least 150 non-English languages. OCR invited comment on what oral interpretation services, if any, we should require and how such approaches appropriately balance the provision of meaningful access to individuals with limited English proficiency and covered entities' flexibility to identify the means of providing such access.

Acceptance of Language Assistance Services Not Required § 92.201(f)

In paragraph (f), we proposed that no individual with limited English proficiency should be required to accept language assistance services, consistent with an individual's right to self-determination. We provided that a

timely, competent language assistance), and IV.L (identifying interpreter standards).

covered entity cannot coerce an individual to decline language assistance services. We also provided that if an individual with limited English proficiency voluntarily declines an offer of language assistance services from the covered entity, a covered entity could denote, in the individual's file or records, the language assistance services offered and the declination.¹⁶⁵

Alternative Approaches

In the proposed rule, we described alternate approaches we considered and requested comment on these approaches and any others to effectuate Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency. For instance, we noted that independent of the proposed requirements of § 92.201, covered entities, including Health Insurance Marketplaces, State agencies administering Medicaid and Children's Health Insurance Program (CHIP) programs, and qualified health plan issuers, must comply with any applicable language access requirements in other laws and regulations.¹⁶⁶ We invited comment on whether the requirements under different authorities should be harmonized and if so, to what extent and how.

We also stated that we considered a regulatory scheme requiring covered entities to provide meaningful access to each individual with limited English proficiency by providing effective language assistance services, at no cost, unless such action would result in an undue burden or a fundamental alteration of the health program or activity.¹⁶⁷

We further noted that we considered a regulatory scheme requiring covered entities to provide a range of language assistance services in the non-English languages spoken by State-wide populations with limited English proficiency that meet defined thresholds. Such thresholds would provide a minimum number of non-English languages in which covered entities would be required to deliver oral interpretation services; to translate written vital documents and Web site content; and to include taglines on vital documents and on Web sites.¹⁶⁸ We requested comment on whether OCR

¹⁶⁵ 80 FR at 54184 (citing HHS LEP Guidance, *supra* note 49, 68 FR at 47318, 47320 (suggesting that recipients consider whether to record the primary language of an individual with LEP or an individual's choice to provide his or her own interpreter)).

¹⁶⁶ The proposed rule discusses these entities' requirements at 80 FR at 54184–85.

¹⁶⁷ *Id.* at 54185.

¹⁶⁸ See *id.*

should require thresholds, and if so, what thresholds should be required, and to what geographic areas or service areas the thresholds should apply. We also sought comment on whether OCR should permit covered entities to implement their obligations with a phased-in approach.

We also noted that we considered a regulatory scheme that would impose enhanced obligations on a subset of covered entities. We sought comment on what characteristics should define covered entities that could have enhanced obligations, such as whether the covered entity is of a certain type or size, has frequent contact with individuals with limited English proficiency, or operates particularly important health programs or activities, among other potential factors. We listed potential categories of covered entities that could have enhanced obligations, such as State agencies administering Medicaid or CHIP; Health Insurance Marketplaces; the Department in its operation of its health programs or activities; or covered entities that have a minimum number of beds, employees, or locations, such as hospitals, nursing homes or skilled nursing facilities, home health agencies, and retail pharmacies (including mail-order pharmacies).¹⁶⁹ We described that under this alternate approach, instead of evaluating each case on its particular facts, the Director would evaluate a covered entity's compliance based on whether the entity provided the range of language assistance services in the non-English languages specified.¹⁷⁰ We invited comment on this proposal.

We further requested comment on whether covered entities should be required to systematically prepare to provide language assistance services in their health programs or activities, such as through the establishment of policies and procedures or through other advance planning mechanisms. We stated that in OCR's experience, covered entities are in a better position to meet their obligations to provide language assistance services in a timely manner to individuals with limited English proficiency when those entities identify, in advance, the types and levels of services that will be provided in each of the contexts in which the covered entity encounters individuals with limited English proficiency.

OCR noted that an advance planning requirement could require each covered entity to identify all resources for providing language assistance services; annually assess the frequently-

encountered or highly prevalent languages in the service area of the health program or activity; establish written procedures to which frontline staff could refer when encountering individuals with limited English proficiency; and monitor and oversee the quality of language assistance services provided. We also noted that an advance planning requirement could require each covered entity to build its capacity to provide language assistance services to meet the needs of the national origin populations that the entity serves. We requested comment on the types of advance planning mechanisms, if any, that should be required and why.

In the proposed rule, OCR advised that covered entities that are already developing or implementing language access plans, or otherwise assessing their language assistance needs, should continue such efforts. However, OCR stated that engaging in such planning is not a defense for failing to provide language assistance services to any particular individual at all, or in an untimely manner, if such services are reasonable steps to provide meaningful access. We advised that covered entities that are conducting advance planning should consider how they can ensure that language assistance services are available in their health programs and activities as they simultaneously improve their operational capacities to provide effective language assistance services into the future.

The comments and our responses regarding § 92.201 are set forth below:

Overall, commenters supported the proposed rule's inclusion of specific provisions addressing meaningful access for individuals with limited English proficiency. We received numerous comments written in non-English languages submitted by individuals with limited English proficiency who expressed how essential it is to have language assistance services, at no cost, to understand forms, invoices, and medication instructions. Many comments from the health care provider and insurance industry, as well as from organizations representing individuals with limited English proficiency, agreed that it is essential that individuals, regardless of national origin, be able to access covered entities' health programs and activities. We received many comments, however, regarding the scope and parameters of covered entities' obligations under the final rule.

Comment: Many commenters recommended revising the categories of individuals to whom a covered entity has an obligation to take reasonable

steps to provide meaningful access. Specifically, commenters recommended that a covered entity's obligation should apply to those "eligible to be served" or "likely to be affected by" the covered entity's health programs and activities. Commenters suggested that proposed § 92.201(a), which stated that the obligation of a covered entity runs to those who the entity "serves or encounters in its health programs and activities," unduly narrowed the scope of the covered entity's obligation.

Response: In response to commenters' recommendations, we have replaced the phrase "that it serves or encounters" with "eligible to be served or likely to be encountered." We agree with commenters that a covered entity must be prepared to take reasonable steps to provide meaningful access to individuals beyond those who actually walk into, or contact, that entity. Where a covered entity is likely to encounter, but is unprepared to assist, individuals of particular national origin groups in the languages in which they communicate, those individuals are unlikely to seek services from, or participate in, the entity's health programs or activities, thereby perpetuating barriers to individuals' access to care.

We chose the phrase "eligible to be served or likely to be encountered" because it is one of the formulations in the HHS LEP Guidance of the population to which a covered entity has an obligation.¹⁷¹ In addition, commenters' proposal that a covered entity's obligation applies to individuals "likely to be affected by" the covered entity's health programs and activities gave covered entities less concrete guidance about their obligations relative to the phrase "likely to be encountered."

Comment: Numerous commenters recommended that OCR revise the general obligation in § 92.201(a) to require that covered entities "provide meaningful access" to each individual with limited English proficiency rather than "take reasonable steps to provide meaningful access." Commenters explained that because "meaningful access" is already a subjective standard, requiring "reasonable steps to provide meaningful access" substantially dilutes covered entities' obligations to provide language assistance services.

These commenters suggested that language assistance should be provided in every situation and that oral interpretation, in particular, should be provided "on demand." Commenters

¹⁶⁹ See *id.*

¹⁷⁰ See *id.*

¹⁷¹ See HHS LEP Guidance, *supra* note 49, 68 FR at 47314, 47320, 47322.

suggested that the final rule make this basic obligation clear because some covered entities turn away individuals with limited English proficiency, stating that the entity does not provide language assistance services. For instance, one commenter shared that it is common for individuals with limited English proficiency to use a hospital emergency department as a source of primary care because the individuals' physicians do not offer qualified interpreters for individuals with limited English proficiency. Commenters also suggested that the Director's weighing of the illustrative factors set out in § 92.201(b) should focus exclusively on whether the covered entity provided the appropriate type, form, and manner of language assistance.

Response: We decline to modify the general obligation in § 92.201(a) because it reflects familiar and longstanding requirements applicable under Title VI.¹⁷² In addition, the regulatory scheme provides in § 92.201(b)(1) that in assessing this standard, the Director will consider, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, which places covered entities on notice about the way in which we will evaluate the Title VI standard within the context of health programs and activities. OCR interprets the requirement that covered entities take "reasonable steps to provide meaningful access" to demand that each entity, as an initial step, assess the need to provide language assistance services to each individual with limited English proficiency and respond to that need by providing the appropriate language assistance services on a timely basis.

As we stated in the proposed rule, safe and quality health care requires an exchange of information between the health care provider and patient for the purposes of diagnoses, treatment options, the proper use of medications, obtaining informed consent, and insurance coverage of health-related services, among other purposes.¹⁷³ This

exchange of information is jeopardized when the provider and the patient speak different languages and may result in adverse health consequences and even death.¹⁷⁴ Indeed, the provision of health care services, by its "very nature[,] requires the establishment of a close relationship with the client or patient that is based on sympathy, confidence and mutual trust,"¹⁷⁵ which cannot be established without effective communication.

Comment: Some commenters expressed concern about the potential financial and administrative burden to provide language assistance services. Many of these commenters expressed support for the proposed rule's inclusion of specific provisions addressing access for individuals with limited English proficiency but also urged that public and private health insurance issuers update medical codes and fee schedules to allow providers to receive reimbursement for the provision of language assistance services.

Some commenters offered proposals for minimizing the costs to covered entities for providing language assistance services—oral interpretation services in particular. These recommendations included that OCR facilitate access to telephonic oral interpretation, at no cost to covered entities, and that OCR ensure that covered entities have adequate funding to provide qualified interpreters for individuals with limited English proficiency.

Response: We appreciate hearing commenters' concerns and having the benefit of commenters' recommendations to lessen potential cost and administrative barriers that covered entities may face. It is beyond the scope of this rulemaking to adopt recommendations that OCR fund qualified interpreters or direct issuers to modify medical codes and fee schedules to reimburse health care providers for

their provision of language assistance services.¹⁷⁶

OCR encourages covered entities to work together to leverage their ability to provide language assistance services in the most cost-effective and efficient ways to meet their respective obligations under § 92.201(a) before using costs as a reason to limit language assistance services.¹⁷⁷ OCR also encourages professional associations and organizations to consider what role they can play in helping their members meet the requirements of § 92.201; we provided similar encouragement in the HIPAA Privacy Rule.¹⁷⁸

We further remind State agencies receiving Federal financial assistance for Medicaid and the Children's Health Insurance Program that States may claim Federal matching funds for the costs of written translation and oral interpretation as administrative expenses or as medical assistance-related expenses.¹⁷⁹ Further, increased

¹⁷⁶ We note, however, that the Department's National Stakeholder Strategy for Achieving Health Equity identifies financing and reimbursement for "health interpreting services" as a strategy to achieve the goal of improving cultural and linguistic competency. See U.S. Dep't of Health & Human Servs., Office of Minority Health, National Partnership for Action to End Health Disparities, National Stakeholder Strategy for Achieving Health Equity, Section 3, 131 (2011), http://minorityhealth.hhs.gov/npa/files/Plans/NSS/NSS_07_Section3.pdf.

¹⁷⁷ We note, for example, that the Washington State Medicaid Interpreter Services Program centralizes the provision of language assistance services to achieve economies of scale. See Washington State Health Care Auth., Interpreter Services Program, www.hca.wa.gov/medicaid/interpreterservices (last visited May 4, 2016). Similarly, through OCR's Effective Communication in Hospitals Initiative, the Kentucky Hospital Association built the capacity to offer its approximately 120 member hospitals access to a telephonic interpretation service contract that offers a volume-based discount rate. See Kentucky Hospital Association, Effective Communication in Hospitals, http://www.kyha.com/CM/Initiatives/Safety_and_Quality_Resources/Effective_Communication_in_Hospitals.aspx (last visited May 4, 2016). Although OCR cannot certify that these approaches uniformly enable entities to meet the requirements of Section 1557, they do represent examples of the types of collaborative action that covered entities may consider.

¹⁷⁸ Standards for Privacy of Individually Identifiable Health Information, 65 FR 82462, 82749 (Dec. 28, 2000) (final rule) (codified at 45 CFR pts. 160 and 164) (encouraging professional associations to assist their members in developing policies and procedures required under the Privacy Rule); Standards for Privacy of Individually Identifiable Health Information, 64 FR 59918, 59992 (Nov. 3, 1999) (proposed rule) (encouraging professional associations to assist their members in developing policies and procedures required under the Privacy Rule).

¹⁷⁹ U.S. Dep't. of Health & Human Servs., Center for Medicare & Medicaid Servs., Increased Federal Matching Funds for Translation and Interpretation Services under Medicaid and CHIP 1 (Jul. 1, 2010), <http://www.medicare.gov/Federal-Policy-Guidance/downloads/SHO10007.pdf> [hereinafter CMS].

Continued

¹⁷² See *Lau v. Nichols*, *supra* note 154 (interpreting Title VI to require the covered entity to take affirmative steps to provide students with limited English proficiency of Chinese origin with a meaningful opportunity to participate in Federally-funded educational programs); HHS LEP Guidance, *supra* note 49, 68 FR at 47313 ("[T]he failure of a recipient of [F]ederal financial assistance from HHS to take reasonable steps to provide LEP persons with [a] meaningful opportunity to participate in HHS funded programs may constitute a violation of Title VI and HHS's implementing regulations").

¹⁷³ 80 FR at 54183 (citing to the 2000 HHS LEP Guidance, *supra* note 49, 65 FR at 52763). See generally Cindy Brach et al., *Crossing the Language Chasm*, Health Affairs, vol. 24, no.2 424, at 424–25 (2005) (describing the impacts of language barriers

in health care). In addition, the 2014 National Healthcare Quality and Disparities Report Chartbooks include metrics showing disparities between national origin groups, one of which expressly identifies trends of non-English speaking children who need health care for an illness, injury, or condition who sometimes or never got care as soon as wanted. See U.S. Dep't of Health & Human Servs., Agency for Health Care Research & Quality, 2014 National Healthcare Quality and Disparities Report, Chartbook on Health Care for Hispanics at 47, 57 (May 2015), <http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqdr/2014chartbooks/hispanichealth/2014nhqdr-hispanichealth.pdf>; U.S. Dep't of Health & Human Servs., Agency for Health Care Research & Quality, Person- and Family-Centered Care Chartbook, *supra* note 160, at 12.

¹⁷⁴ 80 FR at 54183.

¹⁷⁵ *Id.*

funding may be available when States claim the cost of written translation and oral interpretation as administrative expenses if such language assistance services are provided for the “enrollment, retention, and use of services” for individuals with limited English proficiency eligible for CHIP and for Medicaid-eligible children and their families.¹⁸⁰ In addition, we remind qualified health plan issuers that the ACA requires, as a condition of an issuer’s health plan receiving certification as a qualified health plan, that the issuer implement a quality improvement strategy for the qualified health plan that provides increased reimbursement or other incentives for the implementation of activities to reduce health and health care disparities, including through the use of language services.¹⁸¹ We encourage health insurance issuers to structure their health plan payment structures to consider health care providers’ expenses in providing language assistance services.

We decline to accept the recommendation that OCR facilitate access to telephonic oral interpretation services for all covered entities. Such facilitation is beyond the scope of the Federal government’s role and is an impractical solution to address the needs of diverse Section 1557 covered entities. However, OCR does share best practices and useful resources, such as through the Federal government’s Interagency Working Group on Limited English Proficiency, at www.LEP.gov.

Comment: We received numerous comments on whether the final rule should include an advance planning requirement for covered entities to be systematically prepared to provide language assistance services in their health programs and activities. The vast majority of these comments recommended that the final rule include such an advance planning requirement—specifically, the development and implementation of a language access plan that addresses the needs of the limited English proficient population in the service area of a

covered entity’s health program or activity. Commenters reasoned that a regulatory requirement is the most effective method of holding covered entities accountable for engaging in meaningful advance planning.

One commenter observed that many covered entities already evaluate the type of language assistance services they are obligated to provide, pursuant to the current HHS LEP Guidance, and thus that codifying this requirement would not impose a significant additional burden on covered entities. This commenter also asserted that an advance planning requirement is analogous to the approach of § 92.7, which requires certain covered entities to have a grievance procedure in place. Another commenter shared that in updating her employer’s language access plan, the availability of online tools and resources greatly reduced the commenter’s anticipated burden of what advance planning would require.

We received many comments recommending that the final rule identify specific required components of a language access plan, including the types of language access services the covered entity will provide and in what languages, based on the languages spoken by eligible individuals with limited English proficiency in the covered entity’s service area. One commenter underscored that to increase efficiency and maximize cost savings, a language access plan should identify multiple types of language assistance services that a covered entity can use for different situations or even within one encounter. This commenter asserted that relying on just one kind of language assistance service may not be appropriate for all communications.

Another commenter recommended that the final rule mirror California’s regulations on advance planning mechanisms for the provision of language assistance services.¹⁸² This commenter stated that, consistent with California’s regulations, OCR should require that language access plans identify all points of contact with individuals with limited English proficiency; provide a procedure for recording individuals’ primary language; identify vital documents; provide a procedure for the translation of vital documents; provide a procedure to request translation of specific other documents; require training on language access services for all staff likely to have

contact with individuals with limited English proficiency; require the assessment of the qualifications of bilingual/multilingual staff; and adopt written policies and procedures regarding the provision of language assistance services, including a procedure for contracting with language service vendors. Other commenters agreed that prior to using individuals to provide interpretation or translation services, covered entities should be required to evaluate or verify the individuals’ knowledge, skills and abilities to confirm that they meet the definition of a qualified interpreter or a qualified translator for an individual with limited English proficiency.

We received a small number of comments opposing a requirement for advance planning. One commenter acknowledged that a language access plan is important in ensuring that covered entities are systematically prepared to provide language assistance services but recommended that OCR should merely encourage, not require, advance planning activities. The commenter observed that developing a language access plan may be too burdensome for small covered entities.

Response: Based on the comments received, we have added a factor—the only illustrative factor in § 92.201(b)(2)—that requires the Director to consider, if relevant, whether the entity has developed and implemented an effective written language access plan, appropriate to its particular circumstances. The language “appropriate to its particular circumstances” conveys our recognition that the nature and extent of the voluntary planning in which a covered entity may choose to engage will vary depending on the entity’s particular health programs and activities, its size, its geographic location, and other factors. A language access plan need not be long, complex, or burdensome.

We note that a written language access plan has long been recognized as an essential tool to ensure adequate and timely provision of language assistance services, including compliance with the general obligation in § 92.201(a) and the quality standards in § 92.201(d)–(f). For instance, for over 15 years, Executive Order 13166 has required each Federal agency to create and implement a language access plan responsive to the needs of the limited English proficient population it serves.¹⁸³ Moreover, the

Increased Federal Matching Funds]; *id.*, Recently Released Policy Guidance—CHIPRA and the ACA, Information Bulletin 1–2 (Jul. 9, 2010), <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/07-09-2010-CHIPRA-and-ACA.pdf> [hereinafter CMS Information Bulletin 7/9/10].

¹⁸⁰ CMS Increased Federal Matching Funds, *supra* note 179, at 1–2; CMS Information Bulletin 7/9/10, *supra* note 179, at 1–2; U.S. Dep’t. of Health & Human Servs., Center for Medicare & Medicaid Servs., Information Bulletin 2 (Apr. 26, 2011), <http://www.medicaid.gov/Federal-Policy-Guidance/downloads/Info-Bulletin-4-26-11.pdf>.

¹⁸¹ See 42 U.S.C. 18031(c)(1)(E), (g)(1)(E) (describing qualified health plan certification requirements in a quality improvement strategy).

¹⁸² See 28 CCR 1300.67.04(c) (requiring each health care service plan to develop and implement a language assistance program that contains standards for enrollee assessment; providing language assistance services; staff training; and compliance monitoring).

¹⁸³ E.O. 13166, 65 FR 50121 (2000). In 2011, the U.S. Department of Justice renewed the Federal Government’s commitment to the Executive Order. Office of the Att’y General, U.S. Dep’t of Justice, Federal Government’s Renewed Commitment to Language Access Obligations Under Executive

development and implementation of a written language access plan is consistent with OCR's longstanding enforcement processes¹⁸⁴ and resolution agreements regarding Title VI.¹⁸⁵ Although we are not requiring language access plans, we encourage entities to consider whether and how they can engage in advance planning to facilitate their ability to meet their obligations under § 92.201 to serve individuals with limited English proficiency on a timely basis.

We decline to outline the minimum expectations for a language access plan, if a covered entity chooses to develop and implement one, because that approach would be too prescriptive. Nonetheless, in our experience, effective language access plans often, among other components, address how the entity will determine an individual's primary language, particularly if the language is an unfamiliar one; identify a telephonic oral interpretation service to be able to access qualified interpreters when the need arises; identify a translation service to be able to access qualified translators when the need arises; identify the types of language assistance services that may be required under particular circumstances; and identify any documents for which written translations should be routinely available. OCR remains available to covered entities as a resource for technical assistance in the development and implementation of language access plans in their health programs and activities. HHS offers helpful guidance

on this subject,¹⁸⁶ as does the U.S. Department of Justice.¹⁸⁷ We encourage covered entities to refer to these materials to assist their advance planning activities.

Comment: Many commenters recommended modifications to, and additional clarification regarding, the list of factors that the Director will take into account, if relevant, among other relevant factors in evaluating a covered entity's compliance with its general obligation in § 92.201(a). These comments fall into four main categories. First, many commenters requested that we add additional factors to the list in § 92.201(b)(2)(i)–(v). Commenters were concerned that absent explicit references to these factors, the Director would not, or could not, consider them. Examples of factors that commenters requested that we add include:

- The frequency with which a covered entity encounters, or is likely to encounter, a particular non-English language;
- the impact to the consumer if language assistance services are not provided;
- the extent to which covered entities can lessen their own cost burdens through technology and reasonable business practices, if the Director considers the costs of language assistance services; and
- if and when a covered entity is permitted to choose a less costly language assistance service than the one an individual may request.

Second, many commenters recommended that we combine the “costs of language assistance services” in proposed § 92.201(b)(2)(v) with “[a]ll resources available to the covered entity” in proposed § 92.201(b)(2)(iv) into a single factor because the two are inherently intertwined.

Third, some commenters requested that OCR clarify in the final rule how the factors in proposed § 92.201(b)(2)(i)–(v) would be weighted relative to each other, if relevant and thus evaluated by the Director in a given case. Most commenters who requested clarification

recommended that the costs of language assistance services and the resources available to the covered entity not be weighted more heavily than the other factors or become dispositive.

Fourth, a number of commenters requested clarification on the function that the length and complexity of the communication in proposed § 92.201(b)(2)(i) would have in the Director's evaluation of a particular case.

Response: After considering the comments received, we have revised the final rule to eliminate the illustrative factors and to articulate only one factor: Whether a covered entity has developed and implemented an effective written language access plan appropriate to its circumstances. We agree with some commenters' concerns that including multiple illustrative factors in the regulatory text may create the erroneous impression that the Director will not consider relevant factors absent from § 92.201(b)(2). Were OCR to modify § 92.201(b)(2) to include all factors suggested by commenters, however, the long list of factors might unintentionally create an unworkable regulatory scheme in the attempt to capture any possible factor that might be relevant in some circumstances.

Given these concerns, § 92.201(b)(1)–(2) of the final rule requires the Director to evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue to the individual with limited English proficiency, and requires the Director to take into account all other relevant factors, including whether the entity has developed and implemented an effective language access plan. We have identified this factor in particular to provide a concrete reminder to covered entities that they may wish to take action to prepare to provide language assistance services to the individuals with limited English proficiency that they will serve or encounter. We reiterate, however, that adoption of a language access plan is a voluntary measure that is not required by the rule; we will continue to evaluate, on a case-by-case basis, whether entities have taken reasonable steps to provide meaningful access and will evaluate all relevant factors in making that assessment.

We recognize that the absence of illustrative factors in regulation text may diminish clarity regarding the Director's evaluation of a covered entity's compliance with § 92.201(a). To provide guidance to covered entities on our intended interpretation of § 92.201(b)(2) and to be responsive to

Order 13166 (Feb. 17, 2011) https://www.justice.gov/crt/about/cor/AG_021711_EO_13166_Memo_to_Agencies_with_Supplement.pdf.

¹⁸⁴ For example, as part of the certification process to ensure that recipients of Medicare Part A are in compliance with Title VI, OCR requires Medicare Part A providers to document their written procedures on communicating effectively with individuals with limited English proficiency. U.S. Dep't of Health and Human Servs., Office for Civil Rights, Civil Rights Information Request for Medicare Certification, Form OMB No. 0945–0006, pt. II.7, http://www.hhs.gov/sites/default/files/ocr/civilrights/clearance/ocr_mctap.pdf (identifying written policies and procedures with respect to serving individuals with limited English proficiency as required in a provider's application for Medicare certification).

¹⁸⁵ See, e.g., HHS OCR VRA with Mee Memorial Hosp., *supra* note 82, at pt. IV.B (requiring the development and implementation of a language access policy), pt. IV.C.1 (determining the language needs of the affected population), pt. IV.C.2 (determining the language needs of each individual with limited English proficiency); HHS OCR VRA with Montgomery County DSS, *supra* note 82, at pt. IV.B (requiring the development and implementation of a language access policy), pt. IV.C.1 (determining the language needs of the affected population), pt. IV.C.2 (determining the language needs of each individual with limited English proficiency).

¹⁸⁶ See HHS LEP Guidance, *supra* note 49, 68 FR at 47319–21 (encouraging recipients to develop a language access plan [called an “LEP Plan” in the Guidance]). HHS's updated language access plan may be a useful model for covered entities. See U.S. Dep't of Health & Human Servs., Language Access Plan (2013), <http://www.hhs.gov/sites/default/files/open/pres-actions/2013-hhs-language-access-plan.pdf>.

¹⁸⁷ See U.S. Dep't of Justice, Civil Rights Div., Language Access Assessment and Planning Tool for Federally Conducted and Federally Assisted Programs (May 2011), http://www.lep.gov/resources/2011_Language_Access_Assessment_and_Planning_Tool.pdf. See also the Federal government's Interagency Working Group on Limited English Proficiency, at www.LEP.gov.

comments received on the illustrative factors proposed, the following preamble discussion sets forth a range of factors that may be relevant in any given case.¹⁸⁸

As an initial matter, we note that one of the factors commenters recommended we add, which is the impact to the individual of failing to provide language assistance services, is necessarily encompassed within § 92.201(b)(1) regarding an evaluation of the nature and importance of the health program or activity and the particular communication at issue.¹⁸⁹

Factors that may be relevant in a particular case for the Director to consider pursuant to § 92.201(b)(2) include but are not limited to: the length, complexity, and context of the communication; the prevalence of the language in which the individual communicates among those eligible to be served or likely to be encountered by the health program or activity; the frequency with which a covered entity encounters the language in which the individual communicates; whether a covered entity has explored the individual's preference, if any, for a type of language assistance service, as not all types of language assistance services may work as well as others in providing an individual meaningful access to the covered entity's health program or activity; the cost of language assistance services and whether a covered entity has availed itself of cost-saving opportunities; and all resources available to the covered entity, including the entity's capacity to leverage resources among its partners or to use its negotiating power to lower the costs at which language assistance services could be obtained.

We decline to adopt commenters' suggestions to create a regulatory scheme that assigns particular weight to any specific relevant factor because the Director will consider and weigh all relevant factors pursuant to § 92.201(b)(2) on a case-by-case basis.

Because we have eliminated the factors in proposed § 92.201(b)(2)(i)-(v), it is moot whether OCR should combine the proposed factor on the costs of language assistance services with the proposed factor on resources available

to the covered entity. Nevertheless, costs and resources are intertwined, which is a principle reflected in the HHS LEP Guidance with respect to Title VI¹⁹⁰ and a principle we reiterated with respect to Section 1557 in the proposed rule.¹⁹¹

With respect to commenters' requests for clarification on the relevance that the length and complexity of a particular communication has on the type of language assistance a covered entity should provide, we note that this factor is emblematic of the fact-based nature of the inquiry described in § 92.201(b)(1)-(2). Where a document is long and complex, it may in some cases be necessary for a covered entity to provide a written translation so that an individual with limited English proficiency can refer back to or study it at a later time. In other cases, however, a covered entity may meet the requirements of this section by summarizing the document orally for a qualified interpreter to then convey to the individual with limited English proficiency, if such approach is sufficient to provide the individual with limited English proficiency meaningful access to the information.¹⁹²

Comment: Many commenters supported the requirement in proposed § 92.201(c) that a covered entity provide language assistance services to an individual with limited English proficiency in a timely manner. Some commenters further suggested that the final rule set out specific time frames for the provision of oral interpretation, written translation, and taglines. For instance, some commenters recommended that we revise § 92.201(c) to require oral interpretation immediately upon request, written translations within 30 days after the

English version is finalized, and taglines simultaneously with English documents. These commenters asserted that oral telephonic interpretation services should be available, at a minimum, no more than 30 minutes after a covered entity encounters an individual with limited English proficiency.

Response: We decline to include prescriptive timeframes for the provision of language assistance services. There is no one definition of "timely" that applies to every type of interaction with every covered entity at all times. Consequently, consistent with the overarching framework of § 92.201, a determination of whether language assistance services are timely will depend on the specific circumstances of each case. We reiterate our statement from the proposed rule that language assistance is timely when it is provided at a place and time that ensures meaningful access to persons of all national origins and avoids the delay or denial of the right, service, or benefit at issue.¹⁹³

Comment: Some commenters suggested that the final rule prohibit the use of computer-automated translation. These commenters suggested that reliance on automated translation is not accurate for the highly specialized vocabulary and terminology used in the health care and health insurance settings, especially for less common non-English languages.

Response: We decline to codify a prohibition on the use of automated translation as part of the final rule because such a requirement may unintentionally stifle innovation in this rapidly developing area. Furthermore, depending on the language at issue as well as the content of the translation, some translation technologies are advantageous to facilitate the translation of written content when used along with a qualified translator who independently verifies the accuracy and quality of the translation.¹⁹⁴ For

¹⁹⁰ See HHS LEP Guidance, *supra* note 49, 68 FR at 47315 ("Resource and cost issues, however, can often be reduced by technological advances; the sharing of language assistance materials and services among and between recipients, advocacy groups, and Federal grant agencies; and reasonable business practices." "Large entities and those entities serving a significant number or proportion of LEP persons should ensure that their resource limitations are well-substantiated before using this factor as a reason to limit language assistance.").

¹⁹¹ See 80 FR at 54183.

¹⁹² A third party to the communication, such as a qualified interpreter for an individual with limited English proficiency, would orally interpret the covered entity's oral summary from English to a non-English-language and would not alter, summarize, omit, or distort the oral summary that the covered entity provides or judge which information is relevant or important. See e.g., The Nat'l Council on Interpreting in Health Care, A National Code of Ethics for Interpreters in Health Care 8, 13 (2004), <http://www.ncihc.org/assets/documents/publications/NCIHC%20National%20Code%20of%20Ethics.pdf> (discussing the ethical principle of fidelity to the original message).

¹⁸⁸ Some of these factors were proposed in § 92.201(b)(2)(i)-(v), were suggested by commenters', are grounded in the HHS LEP Guidance, or are staples of the effective communication analysis in § 92.202 of this final rule, consistent with Federal disability rights law.

¹⁸⁹ See HHS LEP Guidance, *supra* note 49, 68 FR 47311, at 47315 (describing how and why a recipient of Federal financial assistance should consider the nature and importance of the program or activity in determining the extent of its language access obligations under Title VI).

¹⁹³ 80 FR 54172, 54183. The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards) emphasize the importance of timely language assistance. U.S. Dep't of Health & Human Servs., Office of Minority Health, The National CLAS Standards, <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53> (last visited May 4, 2016).

¹⁹⁴ Jessica Sperling, Migration Policy Institute, Communicating More for Less: Using Translation and Interpretation Technology to Serve Limited English Proficient Individuals (2011), 12 <http://www.migrationpolicy.org/research/communicating-more-less-using-translation-and-interpretation-technology-LEP> (noting that translation memory programs are used in the public and private sector to increase the efficiency of translating a high-

instance, translation memory software stores segments of previously translated phrases and can improve a qualified translator's efficiency, especially when updating documents.¹⁹⁵

We do, however, agree with commenters' concerns regarding the use of some automatic translation technologies, which "is particularly dangerous, and can lead to very serious misunderstandings and adverse consequences for medical documents."¹⁹⁶ For example, machine translation programs translate text by performing simple substitution of words using statistical techniques, which may produce highly unreliable translations for certain languages and written content.¹⁹⁷ As a result, using automated translation as the only tool for translating written documents would fulfill a covered entity's obligation under § 92.201(a) only if a qualified translator reviewed the translation for accuracy and edited it as needed.¹⁹⁸ OCR encourages covered entities to understand the strengths and weaknesses of the technology and software programs that qualified translators use.¹⁹⁹

Comment: Commenters identified that some covered entities lack policies or practices to confirm or evaluate a staff member's skills as a qualified translator or to serve as a qualified interpreter for an individual with limited English proficiency. For instance, commenters

volume of documents and to assist a qualified translator in improving consistency among translated documents).

¹⁹⁵ *Id.*

¹⁹⁶ Int'l Medical Interpreters Assoc., IMA Guide on Medical Translation, *supra* note 85, at 3.

¹⁹⁷ *Id.* at 3; EM Balk et al., Assessing the Accuracy of Google Translate To Allow Data Extraction From Trials Published in Non-English Languages, (Prepared by the Tufts Evidence-based Practice Center for the Agency for Healthcare Research & Quality, U.S. Dep't of Health & Human Servs.), 12-15, 21-24, Pub. No. 12(13)-EHC145-EF (2013), https://www.effectivehealthcare.ahrq.gov/ehc/products/329/1386/Methods_Paper-Google-Translate_1-17-13.pdf.

¹⁹⁸ This position is consistent with the position on this issue taken by the U.S. Department of Justice and the U.S. Department of Education. See U.S. Dep't of Justice & U.S. Dep't of Educ., Dear Colleague Letter: English Learner Students and Limited English Proficient Parents, 38 n.103 (Jan. 7, 2015), <http://www2.ed.gov/about/offices/list/ocr/letters/colleague-el-201501.pdf>.

¹⁹⁹ For considerations on ensuring the quality of translations, see Kleber Palma, Migration Policy Institute, Strategies to Help Covered Entities Ensure Quality of Translations, <http://www.migrationpolicy.org/programs/language-access-translation-and-interpretation-policies-and-practices/practitioners-corner> (last visited Mar. 23, 2016); Jessica Sperling, Migration Policy Institute, Practitioner's Corner: Drafting Request for Proposals and Contracts for Language Assistance Services, <http://www.migrationpolicy.org/programs/language-access-translation-and-interpretation-policies-and-practices/practitioners-corner-drafting> (last visited May 4, 2016).

stated that they are aware of situations where individuals who are qualified to interpret—but not translate—are nonetheless translating complex documents such as informed consent forms and discharge instructions. Comments recommended that the final rule require covered entities to evaluate staff members' non-English language proficiency and other skills to ensure that they are qualified before permitting them to interpret, translate, or communicate with individuals with limited English proficiency in the individuals' primary languages.

Response: We share commenters' concerns and, in response, have modified the rule in two ways. First, the final rule requires a covered entity to use a qualified translator for translating written content with respect to its health programs and activities. As the Department stated in its LEP Guidance, "[t]he permanent nature of written translations [] . . . imposes additional responsibility on the recipient to take reasonable steps to determine that the quality and accuracy of the translations permit meaningful access by LEP persons."²⁰⁰ We broadened the title of § 92.201(d) to reflect that this paragraph now addresses specific requirements for written translation in addition to oral interpreter services. The text in proposed paragraph (d) addressing specific requirements for oral interpretation is now reflected as paragraph (d)(1); new paragraph (d)(2) addresses the use of qualified translators.

Second, we added a new paragraph (4) to § 92.201(e) to restrict covered entities from relying on staff who do not meet the definition of "qualified bilingual/multilingual staff" in § 92.4. In OCR's enforcement experience, covered entities too frequently rely on staff members who possess only a rudimentary familiarity speaking and understanding a non-English language (for example relying on their "high school" level of language proficiency) to communicate with individuals with limited English proficiency. This can result in miscommunication and the omission of relevant information, which can in turn result in a lower standard of care and raise questions about whether consent provided by an individual with limited English proficiency was truly informed. Similarly, we have found that qualified bilingual staff members sometimes serve as interpreters even though they do not possess the non-verbal skills of interpreting nor adhere

²⁰⁰ HHS LEP Guidance, *supra* note 49, 68 FR at 47317.

to generally accepted principles of interpreter ethics.

Comment: Some commenters recommended that the final rule not restrict covered entities from relying on friends or family of individuals with limited English proficiency to provide oral interpretation, even when the companion is a minor. These commenters noted that some individuals with limited English proficiency prefer to use their companions to interpret; they also observed that minor children are frequently involved in many aspects of their parents' health care; accordingly, commenters stated that awareness of their parents' health care needs may equip children of individuals with limited English proficiency to act as patient advocates for their parents.

In contrast, numerous commenters supported the proposed rule's standards for oral interpretation and the proposed restrictions on certain persons to interpret or facilitate communication. For instance, one health care provider shared that a high risk hospital was unprepared to provide oral interpretation to a woman in labor. The patient's child had to interpret what her mother was saying but the child did not know the proper terminology to understand the provider's medical questions about a fatal high risk condition.

In addition, many commenters who are limited English proficient shared that some covered entities have required individuals to bring their own interpreters, at a cost to the individual. Others shared that family members and children have served as interpreters for them, which has been insufficient because such family members and children do not have the requisite skills to interpret accurately.

Response: We decline to eliminate the specific requirements in § 92.201(d)-(e) of the proposed rule regarding oral interpretation or the restrictions on certain persons to facilitate communication or interpret. Commenters' recommendations run contrary to HHS's longstanding guidance under Title VI²⁰¹ and to OCR's experience and enforcement practices.²⁰² In many circumstances,

²⁰¹ HHS LEP Guidance, *supra* note 49, 68 FR at 47317-18, 47323.

²⁰² See, e.g., Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and the Rhode Island Department of Human Services, OCR Transaction No. 0876828, pt. IV.K. (Jan. 19, 2011) <http://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/ridhhsagreement.pdf> (containing restrictions on the use of family members and friends as interpreters).

family members, friends, and especially children, are not competent to provide quality, accurate oral interpretation. For communications of particularly sensitive information, oral interpretation by an individual's family or friend often also implicates issues of appropriateness, confidentiality, privacy, and conflict of interest. Thus, covered entities may not rely on family members, friends, or other informal interpreters to provide language access services unless the situation meets an applicable exception in § 92.201(e)(2)-(3) of the final rule. This exception sufficiently balances an individual's preferences with an interest in ensuring competent language assistance services by allowing individuals to use accompanying adults to interpret in some circumstances.

Comment: One commenter suggested that entities should be exempt from complying with the HIPAA Privacy Rule when providing a qualified interpreter for an individual with limited English proficiency when required under § 92.201(a) of this final rule. Specifically, the commenter was concerned that Section 1557 covered entities would be forced to use or disclose protected health information in violation of the Privacy Rule when engaging interpreter services.

Response: OCR is responsible for enforcing the HIPAA Privacy Rule in addition to the rule implementing Section 1557. We note that, in most instances, a qualified interpreter will be a business associate or a workforce member of the covered entity. If a qualified interpreter is a business associate, a covered entity may disclose protected health information to the qualified interpreter if it obtains satisfactory assurances that the interpreter will use the information only for the purposes for which the interpreter was engaged and will safeguard the information from misuse. Such satisfactory assurances must be in writing and in the form of a contract between the covered entity and the qualified interpreter. If a qualified interpreter is a workforce member of the covered entity, a covered entity may share information with that interpreter as an employee or another type of agent of the entity (e.g., hired through a contract or on the covered entity's staff as a volunteer).

Determining the relationship between the interpreter and the covered entity is a covered entity's HIPAA obligation and is unchanged by Section 1557 or this part. We encourage covered entities to review OCR's HIPAA Frequently Asked Questions (FAQ) regarding business associates at <http://www.hhs.gov/ocr/>

[privacy/hipaa/faq/business_associates/760.html](http://www.hhs.gov/hipaa/faq/business_associates/760.html), and OCR's HIPAA FAQ regarding interpreters at <http://www.hhs.gov/hipaa/for-individuals/faq/528/can-my-health-care-provider-discuss-my-health-information-with-an-interpreter/>.

Comment: A few commenters suggested that the final rule urge covered entities to provide an in-person qualified interpreter for an individual with limited English proficiency as the default type of oral interpretation. These commenters explained that covered entities should rely on remote interpretation via telephone or video only in urgent situations or if an in-person interpreter is unavailable. These commenters reasoned that use of remote interpretation technologies may miss nuances of the communication and result in less accurate or less comprehensible communication. A few commenters recommended that a covered entity's use of remote interpretation services, via phone or video, be limited to administrative matters that can be addressed in 10 minutes or less. Moreover, in response to comments received in 2013 on OCR's Request for Information on Section 1557, some commenters identified concerns with the use of video remote interpretation services because the video connections used often were of a poor quality.

Response: We believe that commenters' recommendations regarding restrictions on remote oral interpretation are unnecessarily prescriptive and inconsistent with the fact-based, contextualized analysis under Title VI and this final rule. However, in situations where visual cues and other messages depend on physical as well as verbal communication, remote interpretation may not be adequate to provide meaningful access to an individual with limited English proficiency.

To address concerns that video remote interpreting technologies may result in less comprehensible communication, we are setting performance standards in § 92.201(f) of this final rule for video remote interpreting services²⁰³ used for oral

interpretation for an individual with limited English proficiency. These standards are designed to achieve parity with the regulation in the disability rights context regarding video remote interpreting technologies. Thus, the standards in § 92.201(f)(1)-(4) of the final rule closely parallel the standards on video remote interpreting services in § 92.202 regarding effective communication for individuals with disabilities, which in turn rely on the standards under Title II for the use of sign language interpreters.²⁰⁴

Comment: We received a few comments expressing concern about proposed § 92.201(f), re-designated in the final as § 92.201(g), which provides that an individual with limited English proficiency shall not be required to accept language assistance services offered by a covered entity. Some commenters recommended that proposed § 92.201(f) permit a covered entity to require the presence of a qualified interpreter, even if an individual with limited English proficiency has declined language assistance services.

Commenters suggested that when the individual who declines language assistance services is a patient, the health care provider's ability to accurately diagnose medical conditions is undermined. Commenters similarly stated that when the individual who declines language assistance services is a limited English proficient health care decision-maker for a child, that decision-maker would not be able to appropriately consent to, or participate in, a child's treatment plan. These commenters recommended requiring that a covered entity's insistence on a qualified interpreter be made in a non-coercive and culturally-appropriate manner.

Response: OCR interprets proposed § 92.201(f), which this final rule re-designates as § 92.201(g), to allow a covered entity to use a qualified interpreter when it is a reasonable step to provide an individual with limited English proficiency access to the covered entity's health program or activity. Although an individual with limited English proficiency can decline a qualified interpreter for herself, nothing in the rule is intended to bar a

²⁰³ We intend that "video remote interpreting services" used for oral interpretation for individuals with limited English proficiency means the same that it does when used to provide interpretation for individuals with disabilities as defined by reference in § 92.4 of this final rule: "an interpreting service that uses video conference technology over dedicated lines or wireless technology offering high-speed, wide-bandwidth video connection that delivers high-quality video images as provided in [28 CFR] 35.160(d)." See *infra* § 92.4 (defining "auxiliary aids and services" to include "video

remote interpreting services," as defined in Title II of the ADA, 28 CFR 35.104).

²⁰⁴ 28 CFR 35.160(d)(1)-(4). In contrast to 28 CFR 35.160(d)(2), which regulates the size of the video image to ensure that the screen shows one's face, arms, hands, and fingers, paragraph (f)(2) of § 92.201 in this final rule does not regulate the size of the video image because this component is less relevant for oral interpretation between English and non-English languages.

provider from using a qualified interpreter to assist the provider in communicating with, and assuring appropriate treatment to, the individual.²⁰⁵ As a result, OCR does not intend for § 92.201(g) of the final rule to restrict a covered entity from using a qualified interpreter in either of the situations commenters raised. We also remind covered entities that, as we stated in the proposed rule, they may not discourage individuals with limited English proficiency from accepting language assistance services.

Comment: Some commenters proposed that OCR regulate the data sources to which covered entities may refer to assess the prevalence of languages spoken by individuals with limited English proficiency in their respective service areas. Commenters also recommended that OCR provide covered entities with resources, such as data-driven maps of languages spoken by limited English proficient populations in their respective service areas, to facilitate covered entities' assessments.

Response: We decline to accept commenters' suggestions, but we support covered entities' efforts to assess the language needs of their respective service areas. An assessment is a foundational best practice for a language assistance services program.²⁰⁶ Data sources that may be useful include data from the United States Census Bureau, particularly the American Community Survey; utilization data from the covered entity's files for individuals with limited English proficiency; data from State and local governments; school system data; data from community agencies and organizations; and data from refugee or immigrant serving agencies.²⁰⁷ Covered entities, however, are in the best position to determine what local or regional data sources are best suited to their needs. When using any data source, covered entities should look at

the reliability, stability, and currency of the data to understand its strengths and weaknesses.

Comment: Many commenters provided feedback on OCR's request for comments on whether the final rule should set thresholds for the non-English languages in which covered entities must provide a range of language assistance services. The majority of comments on this issue focused on thresholds for the translation of vital documents.

Commenters supporting thresholds for written translation suggested that this policy improves access for individuals with limited English proficiency; streamlines OCR's compliance determinations; eliminates ambiguity by providing clear, quantifiable standards for covered entities; is consistent with other Departmental regulations specifying thresholds for written translation; and mitigates the risk that covered entities forgo written translation entirely.

Commenters recommended a variety of thresholds, such as those requiring translation based on the number of languages, percentage of language speakers, or the number of language speakers in a covered entity's service area, or composite thresholds mixing and matching these approaches. Some commenters simply stated that vital documents should be translated into the most commonly encountered languages in a covered entity's service area. Others suggested that OCR codify the threshold for translation of vital documents that is articulated as a safe harbor in the HHS LEP Guidance: translation into languages spoken by at least 1,000 persons or at least 5% of those present in the service area.²⁰⁸ Other commenters asserted that numeric thresholds for translation are too rigid to be applied universally, and recommended that the final rule focus on translating materials for certain health programs, such as clinical research or health insurance programs.

Response: Although we have extensively considered whether to include thresholds for written translation and/or oral interpretation as either a safe harbor or as an across-the-board minimum requirement, we decline to set such thresholds in the final rule. First, although thresholds

may improve access for some national origin populations, the approach does not comprehensively effectuate Section 1557's prohibition of national origin discrimination. Setting thresholds would be both under-inclusive and over-inclusive, given the diverse range, type, and sizes of entities covered by Section 1557 and the diverse national origin populations within the service areas of entities' respective health programs and activities.

For instance, a threshold requiring all covered entities, regardless of type or size, to provide language assistance services in languages spoken by 5% of a county's limited English proficient population could result in the provision of language assistance services in more languages than the entity would otherwise be required to provide under its obligation in § 92.201(a). This threshold would apply regardless of the number of individuals with limited English proficiency who are eligible to be served or likely to be encountered by the covered entity's health program or activity and regardless of the covered entity's operational capacity. Similarly, this threshold could leave behind significant numbers of individuals with limited English proficiency, served by a covered entity's health program or activity, who communicate in a language that constitutes less than 5% of the county's limited English proficient population.

Although some Departmental regulations set thresholds, those regulations address entities or health programs of similar sizes and types, such as qualified health plan issuers, Marketplaces, Medicare Advantage, and Medicare Part D. In comparison, Section 1557 and this part regulate more diverse types of covered entities with potentially more diverse limited English proficient populations. We are concerned that significant limited English proficient populations might receive no or inadequate language assistance services under a threshold-based regulation. We are also concerned about the burden an across-the-board translation threshold might place on small covered entities.

Moreover, we value the flexibility inherent in the contextualized approach we have chosen to assess compliance with the requirement to take reasonable steps to provide meaningful access. We thus decline to impose the prescriptive standards recommended by the commenters as inconsistent with this customized regulatory approach.

Comment: We received many comments in response to whether the rule should require enhanced language access obligations for some types of

²⁰⁵ This understanding is consistent with the HHS LEP Guidance, *supra* note 49, 65 FR at 47318 (stating that even if an individual with limited English proficiency declines a qualified interpreter, where precise, complete, and accurate information is critical, or where the competency of the preferred interpreter that the individual desires to use is not established, "a recipient may want to consider providing its own, independent interpreter, even if the LEP person wants to use his or her own interpreter as well.").

²⁰⁶ See HHS LEP Guidance, *supra* note 49, 68 FR at 47314, 47320.

²⁰⁷ See Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Memorial Health System, OCR Transaction No. 08-79513, pt. V.B.1.b, http://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/mhs_vra.pdf (last visited Mar. 11, 2016) (listing data sources for an assessment of language needs).

²⁰⁸ The safe harbor further provides that if a language group with fewer than 50 individuals constitutes 5% of the recipient's service area, the recipient is not obligated to translate written materials but must provide written notice in the primary language of that language group of the right to receive oral interpretation, at no cost to the individual. HHS LEP Guidance, *supra* note 49, 68 FR at 47319.

covered entities and if so, what types of entities should be subject to enhanced obligations. Some commenters suggested that enhanced obligations would be appropriate for certain covered entities that offer particularly significant or large health programs or activities, such as the Department, State agencies administering Medicaid or CHIP, Marketplaces, and qualified health plan issuers. These commenters asserted that these covered entities possess both the resources and the means to meet enhanced obligations and that they can leverage economies of scale. The commenters also asserted that imposing enhanced obligations on these entities would benefit smaller entities by making translated documents more widely available.

Commenters also addressed the scope of enhanced language access obligations, suggesting that such obligations should include requiring oral interpretation in at least 150 languages and the translation of documents into languages spoken by individuals with limited English proficiency when such individuals constitute 5% of, or 500 people in, the State population or the covered entity's service area.

A few commenters opposed enhanced language access obligations for certain types of covered entities. Specifically, one commenter asserted that there was no principled reason for retail pharmacies, which the proposed rule listed as an example of a covered entity that could have enhanced obligations under § 92.201,²⁰⁹ to be subject to enhanced language access obligations.

Response: We reiterate our view that the contextualized approach in § 92.201 best considers both the needs of individuals with limited English proficiency and the potential burden on covered entities. Creating uniform, across-the-board requirements for particular categories of covered entities is, like thresholds, both under-inclusive and over-inclusive. For example, some smaller entities may operate in areas with significant concentrations of individuals with limited English proficiency; these entities may need to provide a broader scope of language assistance services to meet the requirements of § 92.201 than do other entities of similar size in less diverse areas. Similarly, State agencies that administer Medicaid and CHIP programs will differ with respect to the size and diversity of the limited English proficient populations they serve and the resources available to them.

Comment: Some commenters asserted that HHS, other Federal Departments, and States already heavily regulate health insurance issuers covered by Section 1557, thus subjecting them to multiple language access regulations at the State and Federal level. These commenters recommended two policy approaches to streamline Federal and State language access requirements: (1) Harmonize nondiscrimination rules across all Federal and HHS programs to create a national standard; and/or (2) permit a deeming approach that allows compliance with Federal or State language access laws to suffice for compliance with Section 1557, and similarly allow compliance with Section 1557 to suffice for compliance with other Departmental regulations addressing language access. In contrast, numerous commenters supported our fact-specific, contextualized approach and urged consideration of additional factors (*see discussion supra*) that would require the more robust provision of language assistance services.

Response: The Department understands the potential for confusion and burden that can be imposed where entities are subject to multiple sets of overlapping requirements. For this reason, we have harmonized, to the extent possible, the tagline requirement in § 92.8(d)(1) with the tagline requirement applying to Marketplaces and qualified health plan issuers under 45 CFR 155.205(c)(2)(iii)(A).²¹⁰ We will continue to coordinate as appropriate within HHS and with other Federal departments to ensure that the application and enforcement of requirements under Section 1557 is consistent with other provisions of Federal law or regulations.

However, we decline to adopt an approach that otherwise automatically harmonizes nondiscrimination rules or deems compliance with other laws sufficient for compliance with Section 1557. As we noted above in the discussion of deeming in the General Comments, it is common for entities to be subject to multiple State and Federal regulations, even when some of those regulations have been adopted by a single Federal agency. Indeed, even under CMS regulations for instance, Health Insurance Marketplaces,²¹¹ State

agencies administering Medicaid and CHIP programs,²¹² and qualified health plan issuers,²¹³ are subject to multiple differing requirements with regard to language assistance services.

With specific regard to language assistance services, there are likely numerous situations in which a qualified health plan issuer's compliance with the meaningful access provisions of 45 CFR 155.205(c) would suffice to meet the requirements of Section 1557; indeed, there are instances in which 45 CFR 155.205(c) (*e.g.*, requiring that Marketplaces and qualified health plan issuers provide

45 CFR 155.205(a); a Marketplace's Web site, *see id.* 155.205(b); applications, forms, and notices required to be sent by a MarketplaceSM; *see id.* 155.230(b); and a Marketplace's consumer assistance functions, including a Marketplace's outreach and education activities and a Marketplace's Navigator program authorized by 42 U.S.C. 18031(i) and regulated at 45 CFR 155.210, *see id.* 155.205(d) and (e). In making information accessible to individuals with limited English proficiency, Marketplaces must do so through a combination of written translation, oral interpretation, posting of taglines, and translation of certain Web site content. *See* 45 CFR 155.205(c)(2)(i)(A) (oral interpretation), (ii) (written translation), (iii)(A) (taglines), (iv)(A) (translation of certain Web site content). With respect to a Marketplace's Navigator program, Navigators are required to provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the MarketplaceSM, including individuals with LEP. *See* 42 U.S.C. 18031(i)(3)(E) (statutory requirement); 45 CFR 155.210(e)(5) (regulatory requirement).

²¹² State agencies administering Medicaid programs and CHIP have language access obligations under laws independent of Federal civil rights laws. *See, e.g.*, 42 CFR 435.905(a)–(b)(1) (requiring State agencies administering Medicaid programs to provide language assistance services for applicants and beneficiaries who are limited English proficient); 457.340(a) (requiring State agencies administering CHIP to comply with certain regulatory requirements applicable to Medicaid, including 435.905(a)–(b)(1), which requires that program information be accessible to individuals with LEP); 435.1200(f)(2) (requiring States to make their Medicaid Web sites accessible to individuals with limited English proficiency); 438.10(c)(1)–(5) (specifying obligations for States delivering benefits and services through Medicaid managed care plans, including managed care organizations and certain plans themselves, to make written information available in certain non-English languages, to provide oral interpretation, and to notify individuals with limited English proficiency of the availability of language assistance).

²¹³ *See, e.g.*, 42 U.S.C. 18031(e)(3)(B) (requiring health plans seeking certification as qualified health plans to provide certain information, including claims payment and rating practices, cost-sharing, and enrollee and participant rights in plain language, which means language that the intended audience, including individuals with limited English proficiency, can readily use and understand); 45 CFR 155.205(c)(2)(i)(A), (ii), (iii)(A), (iv)(B) (requiring telephonic interpreter services, written translation, taglines, and translations of certain Web site content, respectively, for information provided to individuals with limited English proficiency); 156.250 (requiring meaningful access to certain qualified health plan information in accordance with the standards described in 155.205(c)).

²¹⁰ Qualified health plan issuers are also bound by the tagline requirement in market-wide regulations at 45 CFR 147.136(e) (effective Jan. 19, 2016) described in the preamble to § 92.8, *supra* note 107.

²¹¹ Health Insurance Marketplaces have language access obligations under laws independent of Federal civil rights laws requiring the following to be accessible to individuals with limited English proficiency: a Marketplace's toll-free call center, *see*

²⁰⁹ *See* 80 FR at 54185.

telephonic oral interpretation in 150 languages²¹⁴) might require more than would be required in a particular case under the fact-based analysis we adopt for Section 1557. However, we are concerned that there may be cases in which using CMS regulations alone to define a covered health insurance issuer's obligations could leave significant numbers of individuals with limited English proficiency without any, or adequate, access to language services.

In addition, automatically harmonizing requirements imposed on particular entities regulated by both Section 1557 and other laws that the Department enforces would undermine an equally important form of consistency: consistency in enforcement of the standards of Section 1557 and this part across all of the diverse categories of entities covered under the law.

For these reasons and the reasons discussed in the General Comments *supra*, we decline to adopt an approach that automatically deems compliance with CMS or other Federal regulations to be sufficient to demonstrate compliance with Section 1557. However, in circumstances where qualified health plan issuers' compliance with § 92.201 requires steps in addition to those required for compliance with 45 CFR 147.136 or 155.205, OCR will work with qualified health plan issuers to bring them into compliance with § 92.201. In addition, OCR will consider a qualified health plan issuer's compliance with other applicable regulations in determining the appropriate enforcement action.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions in § 92.201 with several modifications.

In § 92.201(a), we replaced the phrase "that it serves or encounters" with "eligible to be served or likely to be encountered."

In § 92.201(b), we implemented a technical revision in paragraph (b)(1) and we modified paragraph (b)(2). With respect to the technical revision in paragraph (b)(1), we modified this proposed phrase: "the nature and importance of the health program or activity, including the particular communication at issue, to the individual with limited English proficiency" by replacing "including" with the conjunction "and." This technical revision clarifies OCR's intent that the particular communication at

issue will routinely be a component of the Director's evaluation when the Director gives substantial weight to the nature and importance of the health program or activity. In addition, we modified § 92.201(b)(2) to state that the Director, in evaluating compliance, will take into account all relevant factors, which includes whether a covered entity has developed and implemented an effective written language access plan, appropriate to its circumstances. We eliminated paragraphs (i) through (v) of § 92.201(b)(2).

In § 92.201(d), we broadened the title to reflect that this paragraph now addresses specific requirements for written translation in addition to oral interpretation services. The text in proposed paragraph (d) addressing specific requirements for oral interpretation is now reflected under a new paragraph (d)(1). We added paragraph (d)(2) to require covered entities to use a qualified translator when translating written content in paper or electronic form for its health programs or activities.

In § 92.201(e)(2)(i) and (e)(3), we added "for the individual with limited English proficiency" after "qualified interpreter" to conform to the revision of this term as defined in § 92.4 of the final rule. In addition, we added a new paragraph (e)(4) to address restrictions on a covered entity's use of staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency, in their primary languages.

We re-designated paragraph (f) of § 92.201 in the proposed rule as paragraph (g) of § 92.201 in this final rule, and we added a new paragraph (f). New paragraph (f) provides that when a covered entity uses video remote interpreting services as the means to provide an individual with limited English proficiency oral language assistance, the video remote interpreting technology must meet the standards listed in § 92.201(f)(1)–(4) of this final rule.

Effective Communication for Individuals With Disabilities (§ 92.202)

In § 92.202 of the proposed rule, we proposed to incorporate the provisions governing effective communication with individuals with disabilities found in the regulation implementing Title II of the ADA, which applies to State and local government entities and requires covered entities to ensure that communications with individuals with disabilities are as effective as they are with individuals without disabilities. We noted that OCR typically looks to the ADA for guidance in interpreting

Section 504 as the two laws contain very similar standards.

In the proposed rule, OCR considered whether to incorporate the standards in the regulation implementing Title II of the ADA or in the regulation implementing Title III of the ADA, or the standards in both regulations. Standards regarding effective communication under both regulations are very similar. We noted that there are, however, limited differences between the Title II and Title III regulations, regarding limitations on the duty to provide a particular aid or service where doing so may impose undue financial and administrative burdens, and the obligation under the Title II regulation to give primary consideration to the choice of an aid or service requested by the individual with a disability.

OCR proposed to apply the Title II standards to all entities covered under the proposed rule. We noted that although OCR could apply Title II standards to States and local government entities and Title III standards to private entities, we believe it is appropriate to hold all recipients of Federal financial assistance from HHS to the higher Title II standards as a condition of their receipt of that assistance. We also noted that it is appropriate to hold HHS itself to the same standards to which the Department subjects the recipients of its financial assistance.

We also proposed that where the regulatory provisions referenced in § 92.202 use the term "public entity," that term shall be replaced with "covered entity."

The comments and our responses regarding § 92.202 are set forth below.

Comment: A few commenters suggested that HHS urge covered entities to consider the gender preferences of patients for interpreters. These commenters suggested that patients may not be comfortable with interpreters of the opposite gender, particularly in settings that involve nudity such as in an obstetrics and gynecology appointment.

Response: We recognize the commenters' privacy concern, but we decline to accept the commenters' suggestion. We believe that identification with a certain gender specified by the patient is not a characteristic necessary to interpret for an individual with a disability or an individual with limited English proficiency. The definitions of qualified interpreter for an individual with a disability and qualified interpreter for an individual with limited English proficiency set forth in § 92.4 require an

²¹⁴ See 45 CFR 155.205(c)(2)(i)(A).

interpreter who adheres to generally accepted interpreter ethics, which would include respecting a patient's privacy and comporting oneself with discretion and professionalism in sensitive situations such as the settings described by the commenters. We believe that an interpreter of any gender can display these qualities and thus adequately perform the interpretation duties required of him or her. In those cases where an interpreter is unable to provide interpretation consistent with these standards, the interpreter would be unqualified for those reasons. In addition, acceding to the commenter's request could result in gender discrimination, which contravenes the purpose of other provisions of this rule.

Comment: A few commenters suggested that OCR apply cultural competency standards, such as the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS), to entities serving people with disabilities.

Response: Although OCR does not codify the CLAS standards as part of this regulation, OCR agrees that the CLAS standards provide valuable guidance to covered entities regarding the provision of services that are responsive to diverse cultural beliefs and practices, preferred languages, health literacy and other communication needs, and that promote compliance with the final rule. OCR encourages adoption of the CLAS standards by covered entities for interactions with all their patients and not simply for those with disabilities.

Comment: Some commenters suggested that OCR strengthen effective communication regulations by including the proposed provision regarding the restricted use of certain persons to interpret or facilitate communication contained in § 92.201(e) for individuals with limited English proficiency in § 92.202 for individuals with disabilities.

Response: We appreciate the commenters' suggestion, and note that § 92.202 incorporates provisions of the ADA regarding the restricted use of certain persons to interpret or facilitate communication; it is comparable to the provision in the final rule regarding restrictions on the use of certain persons to interpret or facilitate communication with individuals with limited English proficiency.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, including comments regarding the auxiliary aids and services requirement in

§ 92.101(b)(2)(i) (discussed above), we are finalizing the provisions proposed in § 92.202 by re-designating the existing regulation text at § 92.202 as § 92.202(a), and adding a new subsection, § 92.202(b) requiring covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

Accessibility Standards for Buildings and Facilities (§ 92.203)

The Section 504 regulatory provisions incorporated into Subpart B in this regulation contain program accessibility requirements that apply to existing facilities as well as new construction and alterations. In § 92.203 of the proposed rule, we proposed to establish specific accessibility standards for new construction and alterations. We noted that these standards are consistent with existing standards under the ADA.

Under paragraph (a), we proposed that each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based MarketplaceSM shall comply with the 2010 ADA Standards for Accessible Design (2010 Standards), as defined in the ADA Title II regulations,²¹⁵ if construction or alteration was commenced on or after January 18, 2018. We proposed that all newly constructed or altered buildings or facilities subject to this section shall comply with the requirements for a "public building or facility" as defined in Section 106.5 of the 2010 Standards.

We also proposed that new construction and alterations of such facilities would also be subject to the new construction standards found in the Section 504 implementing regulation at 45 CFR 84.23(a) and (b).

Under paragraph (b), we proposed that each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based MarketplaceSM before January 18, 2018 in conformance with UFAS, the 1991 ADA Standards for Accessible Design (1991 Standards), or the 2010 Standards be deemed to comply with the requirements of this section and with 45 CFR 84.23 (a) and (b), cross referenced in § 92.101(b)(2)(i) with respect to those facilities. Thus, we proposed that if the construction or alteration of facilities began prior to the

effective date of paragraph (a) of this section, the facilities be deemed in compliance if they were constructed or altered in conformance with applicable standards at the time of their construction or alteration.

In paragraph (c), we proposed that each building or part of a building that is constructed or altered by or on behalf of, or for the use of, the Department must be designed, constructed, or altered so as to be readily accessible to and usable by individuals with disabilities. We proposed that the definitions, requirements, and standards of the Architectural Barriers Act, as established in Appendices C and D to 36 CFR pt 1191, apply to buildings and facilities covered by this section.

OCR considered adding specific language regarding accessibility standards for medical diagnostic equipment. However, we noted that the United States Access Board is currently developing standards for accessible medical diagnostic equipment and, therefore, we are deferring proposing specific accessibility standards for medical equipment. We further noted that a health program or activity's use of medical diagnostic equipment would be covered by Section 1557 under the general prohibition of discrimination on the basis of disability in § 92.101.

The comments and our responses regarding § 92.203 are set forth below.

Comment: Numerous comments supported requiring immediate compliance with the 2010 ADA Standards for new construction and alterations. Commenters urged that OCR not give covered entities an 18-month grace period for compliance because the 2010 Standards already apply to the vast majority of facilities covered by this proposed rule. They maintained that an approach which emphasizes the uniform application of the 2010 Standards upon publication of the 1557 rule will enable greater consistency among implementing agencies, given the overlapping jurisdiction that OCR has with the Department of Justice.

Response: OCR agrees with the comments in part. Because the great majority of entities covered by the final rule are already subject to the 2010 Standards, the regulation has been revised to require covered entities that were covered by the 2010 Standards prior to the effective date of this final rule to comply with the 2010 Standards for new construction or alterations that commence on or after the effective date of the final rule. However, there may be some entities covered by the final rule that were not covered by the 2010 Standards prior to the effective date of the final rule. For those entities,

²¹⁵ 28 CFR 35.104.

application of the 2010 Standards would be new; thus, these entities are given 18 months to comply with the final rule with respect to new construction and alterations. We anticipate that these changes will have only a de minimis impact on cost as nearly all of the entities affected are already subject to the 2010 Standards.

Comment: Numerous commenters recommended that OCR not deem compliance with the UFAS as compliance with Section 1557 for facilities that were constructed or altered prior to 18 months after publication of the final rule. They stated that the UFAS is functionally deficient for people with disabilities; barriers are permitted under the old standard that negatively affect people with mobility and strength disabilities; and, as recognized in the preamble to the proposed rule, nearly all of the facilities covered under the proposed rule are already subject to the 2010 Standards.

Response: OCR appreciates the concern raised by the commenters and agrees with the reasoning underlying the recommendation. OCR has thus modified the language in § 92.203(b) to state that each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based MarketplaceSM in conformance with the 1991 Standards or the 2010 Standards is deemed to comply with the requirements of the final rule with respect to those facilities, if the construction or alteration was commenced before the effective date of the final rule. Conformance with the UFAS will constitute compliance with the requirements of the final rule only with respect to facilities where construction or alteration was commenced before the effective date of the final rule and only where the facility or part of the facility was not covered by the 1991 Standards or 2010 Standards.

Comment: One commenter recommended that OCR limit the facility accessibility requirements to areas of facilities that actually host consumers (patients of providers, in-person enrollees, etc.) and not apply them to covered entities' facilities more generally. The commenter observed that the ADA standards apply to places of public accommodation, and that if a facility is not public-facing, existing ADA requirements for employees already apply and do not need to be incorporated into this rule. The commenter believed that limiting these requirements to public-facing areas of entities would address consumer needs

without creating undue financial and administrative burdens. As an example, the commenter stated that many issuers operate call centers that do not provide face-to-face services to their consumers; therefore, the commenter asserted, it is unclear why the call center would need to comply with physical facility accessibility standards.

Response: OCR notes that applying the building accessibility requirement to facilities or parts of facilities not used in any manner by customers or other program beneficiaries in most cases would be inconsistent with the limited application of the final rule to employment and employees. Thus, this provision is interpreted in light of the limitations on coverage of employment in § 92.101(a) (2); as such, the building accessibility requirement does not apply to facilities or parts of facilities that are visited only by employees of the covered entity except as provided in § 92.208. We believe that this approach is consistent with the ACA's goal of increasing consumer access to health care services and with Section 1557's focus on discrimination against patients, enrollees and other beneficiaries in health programs and activities.

However, we also note that the ADA applies to employment and, in addition, that nearly all of the entities subject to the facility access requirements in the final rule are also subject to facility access requirements under Section 504. Complaints of discrimination related to program accessibility can be brought by employees under the ADA and Section 504, and entities should ensure that they are in compliance with accessibility requirements, including the 2010 Standards, under the ADA.

Comment: Several commenters recommended that OCR require covered entities to make each of their existing facilities accessible to and usable by persons with disabilities. These commenters were concerned that if the accessibility requirement is not applied to each individual facility, then a large for-profit insurance carrier could decide that, among the great majority of its providers who operate in existing facilities, only a small percentage need to be physically accessible or have accessible equipment. Moreover, commenters expressed concern that those accessible providers could be clustered together in some central location, and whenever a member called member services and mentioned the need for accessibility, that member would be actively directed toward the more limited subset of accessible provider offices.

Response: The change urged by the commenter would constitute a new

requirement that is inconsistent with existing standards under Title II of the ADA and Section 504, neither of which has been interpreted to require each existing facility to be accessible; rather, they require that the recipient operate each program or activity so that, when viewed in its entirety, it is readily accessible to individuals with disabilities.²¹⁶ Thus, we decline to accept the recommendation. We do note that issuers covered by this rule are responsible for ensuring that their health programs provide equal access to individuals without discrimination on the basis of disability. OCR also notes that most providers are recipients of Federal financial assistance from HHS and are themselves independently subject to the nondiscrimination requirements, including program accessibility requirements, in the final rule as well as under Title III of the ADA.

Comment: Some commenters urged that the requirement to comply with accessibility standards be primarily placed on the owners of buildings and facilities, rather than on the providers who rent space. One commenter said that OCR should provide resources and training to small business renters so that they understand what terms in their leases are necessary to ensure that landlords take reasonable responsibility for ensuring their facilities comply with Section 1557.

Response: OCR declines to accept the recommendation to place primary responsibility for compliance with accessibility standards on building owners. Under longstanding legal interpretations of the ADA and Section 504, building owners and lessees each have obligations to refrain from discriminating with respect to program access. OCR also is declining to develop resources and training specifically for small business renters, but notes that the Department of Justice has materials on compliance with accessibility standards under the ADA that may be of use to these entities.²¹⁷ In addition, the ADA National Network in HHS supports ten regional centers that provide information, guidance and training on the ADA through services tailored to meet the needs of business, government and individuals at local, regional and

²¹⁶ See 28 CFR 35.150(a); 45 CFR 84.22(a); *Bird v. Lewis and Clark Coll.*, 303 F.3d 1015, 1021 (9th Cir. 2002), cert. denied, 538 U.S. 923 (2003) ("the central inquiry [under the ADA and Section 504] is whether the program, when viewed in its entirety, is readily accessible to and usable by individuals with disabilities").

²¹⁷ See U.S. Dep't of Justice, ADA Title III Technical Assistance Manual Covering Public Accommodations and Commercial Facilities (1993), § III-1.2000, <http://www.ada.gov/taman3.html>.

national levels.²¹⁸ OCR also will develop and make available, before the effective date of the final rule, training materials that cover requirements related to accessibility for individuals with disabilities.

Comment: Some commenters urged OCR to exempt entities that are places of public accommodation under Title III of the ADA from the requirements for physical accessibility under Section 1557, stating that additional requirements are confusing and burdensome for small providers. Another commenter recommended that if a health program or activity would not, under Title III of the ADA, be required to be in compliance with a given standard under the 2010 Standards, then the health program or activity should also be exempt from that standard for the purposes of Section 1557 enforcement.

Response: While entities subject to Title III of the ADA include both entities that receive Federal financial assistance and those that do not, the final rule applies only to entities that receive Federal financial assistance, as well as the Department and entities established under Title I of the ACA. We believe it is reasonable to hold entities that receive Federal financial assistance to the accessibility requirements under the final rule, regardless of the standards to which they might be subject under Title III.

Comment: Some commenters said that OCR should require covered entities to make publicly available information on whether medical diagnostic equipment is accessible, so that individuals with disabilities can make informed decisions when choosing a health care provider. A number of commenters recommended that new accessibility standards should be applicable only when physicians upgrade or replace their existing equipment.

Response: As the preamble to the proposed rule noted, standards for accessible medical equipment are in development by the Access Board; thus, OCR is not requiring compliance with specific accessibility standards at this time. In the absence of such standards, covered entities are not in a position to advise or publicize whether their equipment complies with particular standards. Nonetheless, we noted and reiterate here that general accessibility standards that apply to health programs and activities apply to medical equipment, and health service providers must ensure that their health programs

and activities offered through the use of medical equipment are accessible to individuals with disabilities.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we have revised § 92.203(a) to state that each covered facility must comply with the 2010 Standards, if the construction or alteration was commenced on or after the effective date of the final rule, except that if a covered facility was not covered by the 2010 Standards prior to the effective date of the final rule, it must comply with the 2010 Standards if the construction was commenced after 18 months after the effective date of the final rule.

For the reasons set forth above and considering the comments received, we have also modified the language in § 92.203(b) to state that each covered facility constructed or altered in conformance with the 1991 Standards or the 2010 Standards will be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction or alteration was commenced before the effective date of the final rule. Further, each covered facility that was constructed or altered in conformance with UFAS will be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction was commenced before the effective date of the final rule and the facility was not covered by the 1991 Standards or 2010 Standards.

Accessibility of Electronic and Information Technology (§ 92.204)

In § 92.204(a), we proposed to require covered entities to ensure that their health programs or activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of an entity's health program or activity.²¹⁹ For example, we stated that a Health Insurance MarketplaceSM creating a Web site for application for health insurance coverage must ensure that individuals with disabilities have an equal opportunity to benefit from the Web site's tool that allows comparison of health insurance coverage options,

quick determination of eligibility, and facilitation of timely access to health insurance coverage by making its new Web site accessible to individuals who are blind or who have low vision.

We noted that this provision is consistent with existing standards applicable to covered entities. Specifically, Section 508 of the Rehabilitation Act requires that electronic and information technology developed, procured, maintained, or used by Federal agencies be accessible for individuals with disabilities. Section 508 applies to HHS administered health programs or activities, including the Federally-facilitated Marketplaces. Section 504, which applies to recipients of Federal financial assistance, including issuers that receive Federal financial assistance, and Titles II and III of the ADA, which apply to State and local government entities and places of public accommodation, respectively, similarly have been interpreted to require that covered entities' programs, services, and benefits provided through electronic and information technology be accessible to individuals with disabilities.²²⁰ In addition, some States have adopted Section 508 or Web Content Accessibility Guidelines (WCAG) standards for State agency Web sites or electronic and information technology more broadly.

In paragraph (b), we proposed to require State-based Marketplaces and recipients of Federal financial assistance to ensure that their health programs and activities provided through Web sites comply with the accessibility requirements of Title II of the ADA. We noted that our proposed regulatory text cross-references the Title II regulations as a whole, therefore incorporating any future changes to the Title II regulations. We also noted that these requirements are informed by the Department's extensive experience with web-based technology through Federal grant-making programs, including programs that provide funds for State infrastructure changes to allow electronic applications for coverage through the Medicaid program and the Health Insurance Marketplaces, provider adoption of electronic health records, and the development of web-based curricula for health care professionals.

In the proposed rule, we explained that based on the Department's prior experience in this field, we believe that

²¹⁸ For more information or to contact your regional center, please see <https://adata.org/> and <https://adata.org/national-network>.

²¹⁹ The terms "undue financial and administrative burdens" and "fundamental alteration" as used in this part have the same meaning that they have under the ADA.

²²⁰ See, e.g., discussion of case law in U.S. Dep't of Justice, Accessibility of Web Information and Services of State and Local Government Entities and Public Accommodations (Advanced Notice of Proposed Rulemaking), 75 FR 43460, 43463 (Jul. 26, 2010).

including an explicit, rather than implicit, requirement for electronic and information technology is necessary to clarify the obligations of covered entities to make this technology accessible. In addition, we noted that absent an explicit requirement for accessible electronic and information technology, people with disabilities might not have opportunities to participate in services, programs, and activities that are equal to and as effective as those provided to others, further exacerbating existing health disparities for persons with disabilities.

Given the existing requirements under Section 504, Section 508, and the ADA applicable to information provided through electronic and information technology as a whole, and given the importance of technologies, such as kiosks and applications, to access to health care, health-related insurance and other health-related coverage, we proposed to include an explicit accessibility requirement that applies to all of a covered entity's electronic and information technology, rather than to web access only. We sought comment on this proposal.

We also proposed a general accessibility performance standard for electronic and information technology, rather than a requirement for conformance to a specific set of accessibility standards. We provided that the application of this general accessibility performance standard would be informed by future rulemaking by the Access Board and the Department of Justice. We sought comment on whether the regulation should impose a general accessibility performance standard for electronic and information technology or require that electronic and information technology comply with standards developed pursuant to Section 508 by the Access Board,²²¹ or the Worldwide Web Consortium's Web Accessibility Initiative's WCAG 2.0 AA.

As noted above, we proposed that covered entities would have a defense to making their health programs and activities provided through electronic and information technology accessible if doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of the health program or activity. In determining whether an action would impose such undue burdens, we proposed that a covered entity must consider all resources available for use in the funding or operation of the health program or activity.

We noted that when undue financial and administrative burdens or a fundamental alteration are determined to exist, the covered entity is still required to provide information in a format other than an accessible electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration, but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

The comments and our responses regarding § 92.204 are set forth below.

Comment: A few commenters objected to § 92.204's focus on individuals with disabilities. These commenters noted that Section 1557's nondiscrimination mandate guards against discrimination on the basis of race, color, national origin, sex, and age, as well as disability. Therefore, these commenters recommended that OCR state in § 92.204 that covered entities must ensure that their health programs or activities provided through electronic information and technology are accessible to individuals in all protected classes, not just individuals with disabilities.

Response: Section 92.204 addresses the unique accessibility issues for individuals with disabilities. However, § 92.204's focus on disability does not limit the application of general nondiscrimination principles to the accessibility of health programs and activities offered through electronic and information technology to other groups. Thus, the general prohibition of discrimination set forth in § 92.101(a) requires the accessibility of health programs and activities offered through electronic and information technology, without discrimination on the basis of race, color, national origin, sex, age, or disability.

Comment: One commenter expressed concern that many patients and clients lack internet connectivity in their homes and communities. This commenter stated that while providers should design web-based tools and resources that are user-friendly, appropriate, and effective for patients and clients with disabilities, the providers will need to use alternative creative means to meet the needs of those they serve who lack such connectivity in their homes or communities.

Response: OCR recognizes that many persons lack internet connectivity in their homes and communities and may therefore be unable to access web-based

tools and resources provided by covered entities, and encourages entities to develop creative means to meet the needs of these individuals.

Comment: Several commenters asked that OCR clarify the scope of the electronic and information technology requirements. Specifically, these commenters asked OCR whether § 92.204's requirements are limited to the provision of health services.

Response: Section 92.204's requirements are coextensive with, and bounded by, the coverage of Section 1557. Thus, the rule requires covered entities to make all health programs and activities provided through electronic and information technology accessible. Accordingly, this requirement reaches activities such as an online appointment system, electronic billing, and comparison of health plans offered by a Health Insurance MarketplaceSM. OCR believes that the regulatory text encompasses this approach.

Comment: A few commenters asked OCR to clarify whether the general requirement under subsection (a) to make health programs and activities that are provided through electronic and information technology accessible applies only to health programs or activities provided through electronic and information technology that are accessed by consumers or also to a covered entity's internal facing electronic information technology. Other commenters urged OCR to limit the application of the general requirement under subsection (a) only to health programs or activities provided through electronic and information technology that are directly related to the activity that made the organization a covered entity and that are accessed by consumers. Conversely, several other commenters recommended that OCR extend the application of subsection (a) to employees of covered entities.

Response: OCR addressed a similar issue in considering facility access requirements above. There, OCR noted that extending the facility accessibility requirement to facilities not used in any manner by customers or other program beneficiaries in most cases would be inconsistent with the limited application of the final rule to employment and employees. Thus, we noted that the facility accessibility requirement is interpreted in light of the limitations on coverage of employment in § 92.101(a)(2).

Similarly, in considering the application of the requirement in the final rule to accessibility of health programs and activities offered through electronic and information technology,

²²¹ 36 CFR pt. 1194.

we are mindful that the final rule has limited application to employment and employees. In consideration of this limitation, we clarify that the accessibility requirements in the final rule are limited to health programs and activities offered through electronic and information technology that is used by consumers or other program beneficiaries and do not apply to electronic and information technology that is used only by employees of a covered entity and that does not affect or impact customers or program beneficiaries, except as provided in § 92.208.

We also note that the ADA and Section 504 apply to employment, and virtually all of the entities subject to the requirement for accessibility of health programs and activities offered through electronic and information technology in the final rule are also subject to similar general accessibility requirements in the ADA and Section 504. Entities covered by the final rule should be mindful of their obligations under these other laws.

Comment: Some commenters recommended that OCR require different standards for accessibility of electronic and information technology for entities covered under Title II of the ADA, which applies to State and local government entities, and entities covered under Title III of the ADA, which applies to places of public accommodation and commercial facilities.

Response: OCR declines to apply different standards under the final rule. As noted above, State or local government entities that are covered under Section 1557 are already subject to the Title II standards. In addition, the other entities covered under Section 1557 are health programs and activities that either receive Federal financial assistance from HHS or are conducted directly by HHS. Although OCR could apply Title II standards to States and local entities and Title III standards to private entities, we believe it is appropriate to hold all recipients of Federal financial assistance from HHS to the higher Title II standards as a condition of their receipt of that assistance. As a result, OCR declines to impose different standards as recommended by the commenters. This approach is consistent with our approach to § 92.202, in which we are applying Title II standards to all entities covered under Section 1557 with respect to effective communication.

Comment: One commenter asked that OCR exempt places of public accommodation under the ADA from the requirements to make electronic and

information technology accessible. Other commenters suggested that the electronic and information technology requirements in the proposed rule are too confusing and burdensome for small providers.

Response: Places of public accommodation covered under the ADA already are required to make health programs and activities offered through electronic and information technology accessible to individuals with disabilities. The ADA does not exempt small providers from this requirement. Thus, the requirements under this final rule should be familiar to entities covered under the ADA.

Comment: Many commenters recommended that OCR require compliance with the accessibility standards set forth in WCAG 2.0, with Level AA as the minimum benchmark. These commenters suggested that compliance with a specific standard would offer clarity to covered entities and consistency to consumers. These commenters also favored WCAG over Section 508 because WCAG is technology agnostic, meaning it is broken down by function rather than product-type, and can apply to future innovations as well as current uses of technology. These commenters also noted that the Access Board is modeling the refreshed Section 508 standards on WCAG 2.0 Level AA, ensuring that HHS's adoption of such a technical standard guarantees that there will be one, universal set of accessibility benchmarks.

Conversely, one commenter stated that OCR should not impose a specific accessibility standard for electronic and information technology, arguing that a specific standard may slow innovation and the establishment of potentially effective electronic information technology alternatives.

Response: OCR has decided not to adopt specific accessibility standards at this time. Nonetheless, we are still requiring covered entities to ensure that health programs and activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of an entity's health program or activity. Thus, when a covered entity chooses to provide a health program or activity through electronic and information technology, the entity must ensure that the technology is accessible as necessary for individuals with disabilities to have equal access to the health program or activity. In our experience, where a covered entity chooses to provide health

programs and activities through electronic and information technology, it is difficult to ensure compliance with accessibility requirements without adherence to standards such as the WCAG 2.0 AA standards or the Section 508 standards. Accordingly, OCR strongly encourages covered entities that offer health programs and activities through electronic and information technology to consider such standards as they take steps to ensure that those programs and activities comply with requirements of this regulation and other Federal civil rights laws. Due to the increasing importance of electronic and information technology in health care and health insurance coverage, OCR will continue to closely monitor this area, including developments in the standards developed by the Department of Justice and the Access Board.

Comment: A few commenters asked that OCR give covered entities at least 24 months to come into compliance with the requirements of § 92.204 because they believe there is a significant shortage of available expertise on electronic and information technology. Other commenters recommended that physicians should not be required to comply with new standards until they are ready to upgrade or purchase a new technology product. Still others asked that OCR delay enforcement pertaining to electronic and information technology until health programs and activities can easily select appropriate accessible technology that has been certified by OCR to comply with established standards for accessible technology.

However, many other commenters urged OCR to reject any requests to delay or phase-in the requirements of § 92.204. These commenters pointed out that § 92.204 builds on and reinforces other longstanding accessibility requirements in Federal law; accordingly, it should not be overly burdensome for covered entities to adjust to the requirements of this rule.

Response: OCR is requiring compliance with the requirements of § 92.204 as of the effective date of this regulation. Section 92.204 largely reflects existing standards under the ADA and Section 504, and accordingly, most covered entities are already required to meet § 92.204's standards. Moreover, and with respect to those few covered entities that were not previously subject to the ADA and Section 504 standards, existing undue burden analysis provides adequate safeguards for covered entities that are unable to comply with the requirements of § 92.204 by the effective date.

Comment: One commenter suggested that the responsibility for redesigning health information and technology to improve accessibility should be placed on software vendors and developers rather than on issuers and providers.

Response: The final rule applies to, among other entities, entities that conduct health programs or activities and that receive Federal financial assistance from HHS. Those entities, consistent with longstanding requirements under the ADA and Section 504, must make health programs and activities offered through electronic and information technology accessible to individuals with disabilities. This obligation is not new. Covered entities are not obligated to redesign health information and technology; accessible technology exists and is available to entities covered by the final rule. Thus, HHS is declining to make the change proposed.

Comment: Several commenters suggested that OCR include a reference to specific ADA regulations requiring effective communication in § 92.204.²²² These commenters noted that some of these regulations are the legal origin of the final rule's statement that covered entities must make health programs and activities provided through electronic and information technology accessible. Although these commenters acknowledged that not all of the regulations concerning auxiliary aids and services will apply in the electronic and information technology context, they believe that the explicit incorporation of relevant aspects of these ADA regulations would inform covered entities of other obligations that they might otherwise overlook, such as the obligation to consult and work with individuals with disabilities as part of the entity's effective communication obligation.

Response: OCR believes that intent is clear in the regulation as written. Although OCR is declining to include a reference to 28 CFR 35.160 and succeeding sections in § 92.204, as proposed by the commenters, these sections are incorporated in § 92.202 of the final rule, addressing effective communication with individuals with disabilities. Covered entities are required to comply with both sections of the final rule.

Comment: A few commenters asked OCR to state that electronic information and technology must be functional so that a person with a disability can enjoy all of the same functionality in an equally effective manner and with

substantially equivalent ease of use as a user without a disability.

Response: OCR is clarifying here that a covered entity's electronic and information technology must be functional as necessary to ensure that an individual with a disability has equal access to a covered entity's health program and activity. We believe that the regulatory text encompasses this approach.

Comment: Several commenters called attention to problems that persons with disabilities frequently encounter when attempting to access health care. For example, one commenter pointed out that health care service providers' Web sites often include content like videos with audio components. The commenter noted that these videos often lack closed captioning or American Sign Language (ASL) translations that would make the information provided in the video accessible to people with hearing-related disabilities. Accordingly, this commenter suggested that OCR modify § 92.204 to require covered entities to caption or provide ASL translations of audio-based content on their Web sites so that all audio based content is accessible for deaf and hard of hearing individuals.

Another commenter pointed out that, when blind patients seek treatment at a doctor's office, they are often expected to make appointments or fill out required documentation expected of new patients using an inaccessible online portal. In these situations, the blind patient is forced to rely on a third party for assistance and, regardless of their personal relationship, disclose confidential information to that person such as the patient's medical history, illnesses, medications, and history of disease or genetic patterns running in the patient's family. Accordingly, this commenter asked that OCR clarify that covered entities need to make online portals accessible so that blind individuals have the same level of privacy and confidentiality as other individuals.

Response: Under the final rule, covered entities must ensure that the health programs and activities they offer through electronic and information technology are accessible to individuals with disabilities. OCR is not prescribing specific standards for ensuring accessibility and so declines to adopt the commenters' recommendation. However, OCR notes that under § 92.202(a), which incorporates 28 CFR 35.160(b)(2), "[i]n order to be effective, auxiliary aids and services must be provided [to individuals with disabilities] . . . in such a way as to protect the privacy and independence of

the individual with a disability." We further remind covered entities to consider the range of accessibility issues that arise for individuals with disabilities and the technology-based solutions that are available to address these issues. The confidentiality of health information is a critical issue, and covered entities must ensure that the private health information of individuals with disabilities is appropriately protected.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.204 without modification.

Requirement To Make Reasonable Modifications (§ 92.205)

In § 92.205, we proposed to require covered entities to make reasonable modifications in policies, practices, or procedures when necessary to avoid discrimination on the basis of disability, unless they can demonstrate that the modification would fundamentally alter the nature of the health program or activity.

We did not receive any significant comments regarding § 92.205. For the reasons set forth in the proposed rule, we are finalizing the provisions proposed in § 92.205 without modification.

Equal Program Access on the Basis of Sex (§ 92.206)

In § 92.206, we proposed that covered entities be required to provide individuals equal access to their health programs or activities without discrimination on the basis of sex and to treat individuals consistent with their gender identity. We proposed that this provision applies to all covered health programs and activities, and prohibits, among other forms of adverse treatment, the discriminatory denial of access to facilities administered by a covered entity. We noted that this proposed approach is consistent with the principle that discrimination on the basis of sex includes discrimination on the basis of gender identity and that failure to treat individuals in accordance with their gender identity may constitute prohibited discrimination.

We proposed one limited exception to the requirement that covered entities treat individuals consistent with their gender identity: That a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one gender based on the fact that the individual's

²²² Commenters wanted OCR to cite to 28 CFR 35.160(a)(1), (2); 35.160(d); 35.163; and 35.164.

sex assigned at birth, gender identity, or gender otherwise recorded in a medical record or by a health insurance plan is different from the one to which such health services are ordinarily or exclusively available. For example, a covered entity may not deny, based on an individual's identification as a transgender male, treatment for ovarian cancer where the treatment is medically indicated.

For clarity and consistency within the final rule, we have made some technical revisions to § 92.206. First, regarding a covered entity being prohibited from denying or limiting health services, we are adding the words "to a transgender individual" after "a covered entity shall treat individuals consistent with their gender identity, except that a covered entity may not deny or limit health services, that are ordinarily or exclusively available to individuals of one gender," to clarify that the exception is limited to transgender individuals. We note that similar to the discussion in § 92.207(b)(3), we recognize that not every health service that is typically or exclusively provided to individuals of one sex will be a health service that is appropriately provided to a transgender individual. Nothing in the rule would, for example, require a covered entity to provide a traditional prostate exam to an individual who does not have a prostate, regardless of that individual's gender identity. But for health services that are appropriately provided to an individual, the covered entity must provide coverage for those health services on the same terms regardless of an individual's sex assigned at birth, gender identity, or recorded gender. Second, we are deleting the phrase "in a medical record" to address concerns that "medical records" could be understood as referring only to clinical notes of a health care provider.

The comments and our responses regarding § 92.206 are set forth below:

Comment: A majority of commenters strongly supported the requirement that covered entities provide equal access to health programs and activities without discrimination on the basis of sex and treat individuals consistent with their gender identity. Several commenters noted that discrimination in access to gender-specific facilities remains one of the most common and harmful forms of sex-based discrimination against transgender people, singling them out for humiliation and causing them to avoid the use of such facilities and the associated medical care. Numerous commenters strongly encouraged OCR to strengthen § 92.206 with explicit protections for individuals with non-

binary gender identities who need access to gender-specific programs and facilities, and to affirm that individuals with non-binary gender identities should be permitted to determine which facilities are appropriate for them.

Response: OCR recognizes the difficulty that individuals with non-binary gender identities may face in accessing gender-specific programs and facilities. The rule makes clear that in order to meet their obligations under § 92.206, covered entities must treat all individuals consistent with their gender identity, including with regard to access to facilities. OCR has revised the definition of "gender identity" to clarify individuals with non-binary gender identities are protected under the rule from all forms of discrimination based on their gender identity. Thus, OCR does not believe that it is necessary to reiterate protections for non-binary individuals in this context.

Comment: Commenters noted that because pregnant women have experienced considerable discrimination in accessing certain health care services such as mental health care and drug treatment services, the final rule should state that equal access without discrimination on the basis of sex includes equal access without discrimination on the basis of pregnancy.

Response: OCR recognizes the difficulty many pregnant people experience in accessing certain health care services. In response to this concern, OCR is clarifying here that the equal program access provision under § 92.206 is simply a specific application of the more general prohibition of discrimination under § 92.101(a). Under both provisions, denial of program access on any of the prohibited bases, including pregnancy or related medical conditions, is prohibited.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provision as proposed in § 92.206 with technical revisions to clarify our intent and ensure consistency with other parts of the final rule.

Nondiscrimination in Health-Related Insurance and Other Health-Related Coverage (§ 92.207)

In § 92.207 of the proposed rule, we provided specific details regarding the prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability in the provision and administration of health-related insurance or other health-related coverage. We proposed that this

prohibition applies to all covered entities that provide or administer health-related insurance or other health-related coverage, including health insurance issuers and group health plans that are recipients of Federal financial assistance and the Department in the administration of its health-related coverage programs. We noted that this section is independent of, but complements, the nondiscrimination provisions that apply to the Health Insurance Marketplaces²²³ and to issuers of qualified health plans²²⁴ under other Departmental regulations, and that entities covered under those provisions and Section 1557 are obligated to comply with both sets of requirements.

Based on the longstanding civil rights principles discussed in connection with the definition of "health program or activity" in § 92.4, we proposed to apply this part to all of the coverage and services of issuers that receive Federal financial assistance, whether those issuers' coverage is offered through the MarketplaceSM, outside the MarketplaceSM, in the individual or group health insurance markets, or as an employee health benefit program through an employer-sponsored group health plan.²²⁵ We provided an example illustrating that an issuer participating in the MarketplaceSM, and thereby receiving Federal financial assistance, that also offers plans outside the MarketplaceSM would be covered by the regulation for all of its health plans, as well as when it acts as a third party administrator for an employer-sponsored group health plan.²²⁶

Paragraph (a) proposed a general nondiscrimination requirement, and paragraph (b) provided specific examples of prohibited actions. Paragraphs (b)(1) and (2) proposed to address the prohibition on denying, cancelling, limiting, or refusing to issue or renew a health-related insurance plan or policy or other health-related coverage, denying or limiting coverage of a claim, or imposing additional cost sharing or other limitations or

²²³ 45 CFR 155.120(c).

²²⁴ 45 CFR 156.200(e); 45 CFR 147.104(e); Public Health Service Act section 2705 (codified at 42 U.S.C. 300gg-4).

²²⁵ Like the proposed rule, the final rule separately addresses employer liability for discrimination in employee health benefit programs at § 92.208.

²²⁶ Where an entity that acts as a third party administrator for an employer's employee health benefit plan is legally separate from an issuer that receives Federal financial assistance for its insurance plans, we proposed to engage in a case-by-case inquiry to evaluate whether that entity is appropriately subject to Section 1557. The final rule addresses this further in the discussions under § 92.2 and § 92.208.

restrictions, on the basis of an enrollee's or prospective enrollee's race, color, national origin, sex, age, or disability, and the use of marketing practices or benefit designs that discriminate on these bases.

In the proposed rule, we did not propose to require plans to cover any particular benefit or service, but we provided that a covered entity cannot have coverage that operates in a discriminatory manner. For example, the preamble stated that a plan that covers inpatient treatment for eating disorders in men but not women would not be in compliance with the prohibition of discrimination based on sex. Similarly, a plan that covers bariatric surgery in adults but excludes such coverage for adults with particular developmental disabilities would not be in compliance with the prohibition on discrimination based on disability.

In paragraphs (b)(3) through (5) of the proposed rule, we proposed to address discrimination faced by transgender individuals in accessing coverage of health services. We proposed in paragraph (b)(3) that to deny or limit coverage, deny a claim, or impose additional cost sharing or other limitations or restrictions on coverage of any health service is impermissible discrimination when the denial or limitation is due to the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded by the plan or issuer is different from the one to which such services are ordinarily or exclusively available.²²⁷ Under the proposed rule, coverage for medically appropriate health services must be made available on the same terms and conditions under the plan or coverage for all individuals, regardless of sex assigned at birth, gender identity, or recorded gender.

In addition, we noted that many health-related insurance plans or other health-related coverage, including Medicaid programs, currently have explicit exclusions of coverage for all care related to gender dysphoria or associated with gender transition. Historically, covered entities have justified these blanket exclusions by categorizing all transition-related treatment as cosmetic or experimental.²²⁸ However, such across-the-board categorization is now

recognized as outdated and not based on current standards of care.²²⁹

OCR proposed to apply basic nondiscrimination principles in evaluating whether a covered entity's denial of a claim for coverage for transition-related care is the product of discrimination. We noted that based on these principles, an explicit, categorical (or automatic) exclusion or limitation of coverage for all health services related to gender transition is unlawful on its face under paragraph (b)(4); in singling out the entire category of gender transition services, such an exclusion or limitation systematically denies services and treatments for transgender individuals and is prohibited discrimination on the basis of sex.

Moreover, we proposed in § 92.207(b)(5) to bar a covered entity from denying or limiting coverage, or denying a claim for coverage, for specific health services related to gender transition where such a denial or limitation results in discrimination against a transgender individual. In evaluating whether it is discriminatory to deny or limit a request for coverage for a particular service for an individual seeking the service as part of transition-related care, we provided that OCR will start by inquiring whether and to what extent coverage is available when the same service is not related to gender transition. If, for example, an issuer or State Medicaid agency denies a claim for coverage for a hysterectomy that a patient's provider says is medically necessary to treat gender dysphoria, OCR will evaluate the extent of the covered entity's coverage policy for hysterectomies under other circumstances. We noted that OCR will also carefully scrutinize whether the covered entity's explanation for the denial or limitation of coverage for transition-related care is legitimate and not a pretext for discrimination.

We noted that these provisions do not, however, affirmatively require covered entities to cover any particular procedure or treatment for transition-related care; nor do they preclude a covered entity from applying neutral standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner.

We invited comment as to whether the approach of § 92.207(b)(1)–(5) is over- or underinclusive of the types of potentially discriminatory claims denials experienced by transgender individuals in their attempts to access coverage and care, as well as on how

nondiscrimination principles apply in this context.

Paragraph (c) of § 92.207 of the proposed rule provided that the enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a) of this section. Paragraph (d) of the proposed rule provided that nothing in § 92.207 is intended to determine, or restrict a covered entity from determining, whether a particular health care service is medically necessary or otherwise meets applicable coverage requirements in any individual case.

The comments and our responses regarding § 92.207 are set forth below.

Comment: Numerous commenters requested clarification regarding the rule's applicability to various health programs or activities that are regulated under other Federal requirements and recommended that OCR deem health programs and activities that comply with existing Federal regulations as in compliance with, or exempt from, Section 1557. For example, commenters requested that compliance with CMS regulations pertaining to qualified health plans or insurance benefit design, such as prescription drug formularies designed by a pharmacy and therapeutics committee,²³⁰ be deemed compliance with the final rule. Numerous commenters also requested that OCR harmonize its language access requirements with existing CMS regulations. This is addressed in the discussion of § 92.201.

In addition, other commenters sought clarification as to the applicability of the rule to wellness programs²³¹ and value-based insurance designs²³² that are regulated by other Federal departments and agencies, and similarly requested that compliance with other Federal laws regarding these programs be deemed compliance with this final rule. Conversely, regarding employer

²³⁰ 45 CFR 156.122(a)(3) (for plan years beginning on or after Jan. 1, 2017).

²³¹ U.S. Dep't of the Treasury, U.S. Dep't of Labor, and U.S. Dep't of Health & Human Servs., Incentives for Nondiscriminatory Wellness Programs in Group Health Plans (Final Rule), 78 FR 33158 (June 3, 2013).

²³² For a discussion of Value-Based Insurance Design, see Affordable Care Act Implementation FAQs Set 5, Q1, http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html (last visited May 4, 2016); U.S. Dep't of the Treasury, Dep't of Labor, and U.S. Dep't of Health & Human Servs., Coverage of Certain Preventive Services Under the Affordable Care Act, Final Rule, 80 FR 41318, 41321 (July 1, 2015); and U.S. Dep't of Health & Human Servs., Center for Medicare & Medicaid Servs., Medicare Advantage Value-Based Insurance Design Model (Sept. 1, 2015), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-09-01.html>.

²²⁷ We note that under § 92.207(a), a covered entity would be barred from denying coverage of any claim (not just sex-specific surgeries) on the basis that the enrollee is a transgender individual.

²²⁸ Liza Khan, *Transgender Health at the Crossroads*, 11 Yale J. Health Pol'y L. & Ethics 375, 393 (2011).

²²⁹ See *infra* note 263. See also discussion in the proposed rule at 80 FR at 54189–90.

wellness programs, one commenter wanted OCR to expressly prohibit covered entities from implementing outcomes-based employee wellness programs that base financial rewards or penalties on outcome standards that are coextensive with or directly related to a disability, such as an outcome standard related to high glucose levels, which are directly related to diabetes.

Response: For the same reasons discussed in connection with the General Comments above,²³³ we reject the recommendation to deem health programs or activities that comply with other Federal regulations as automatically in compliance with, or exempt from, the final rule. As a general matter, OCR does not view a covered entity's compliance with other Federal regulations, adopted with different requirements and for different purposes, as determinative of a covered entity's compliance with Section 1557 or other Federal civil rights laws that we enforce. Moreover, deeming compliance in this context must be considered in light of the potential harmful consequences to consumers' health that may occur if covered entities do not adhere to civil rights obligations.

While we reject deeming, OCR will consider a covered entity's compliance with other applicable Federal laws in evaluating a covered entity's compliance with this final rule, and will continue to coordinate with other Federal agencies to promote consistency and avoid duplication in enforcement efforts.

Further, we clarify that evidence-based insurance designs and wellness programs offered through covered entities, such as a health insurance issuer or a group health plan that receives Federal financial assistance, are health programs or activities that are subject to the final rule. We decline to expressly prohibit a particular type of practice by wellness programs in the final rule, as complaints will be reviewed on a case-by-case basis. We note that CMS has made clear that covered entities are responsible for ensuring compliance with other applicable Federal and State laws, including nondiscrimination obligations under Federal laws.²³⁴ We remind covered entities that employer-sponsored wellness programs are considered an employee health benefit

program and that employers will be subject to liability for discrimination in such programs under the circumstances identified in § 92.208.

Comment: Several commenters expressed concern that covered entities would not be able to revise their health insurance coverage or other health coverage to comply with the regulation within 60 days after publication, and requested that the effective date of the final rule, in particular § 92.207, be delayed until January 1, 2017 or 2018.²³⁵ These commenters explained that health insurance plans are filed for review with CMS and State insurance regulators during the year before the calendar year in which the plan is offered for sale. Thus, depending on the publication date of the final rule, the commenters suggested that delaying the effective date to plan years (in the individual market, policy years) beginning in 2017 or 2018 would be necessary for issuers to avoid the administrative challenges associated with applying the final rule's requirements in the middle of a plan year or policy year, including amending benefit designs, revising premium rates if applicable, and refiling the products for review with CMS and State insurance regulators. In addition, the commenters noted that issuers are not permitted to adjust rates mid-year for some insurance products.

By contrast, one commenter supported maintaining the proposed effective date, arguing that the benefits of more immediate implementation of the final rule outweigh any expenses or confusion associated with mid-year policy revisions.

Response: We appreciate the concerns expressed by the commenters but we are maintaining the effective date as 60 days after the date of publication of the final rule, except in the limited circumstances described below. Section 1557 has been in effect since its passage as part of the ACA in March 2010, and covered entities have been subject to its requirements since that time. To delay implementation of the final rule would delay the existing and ongoing protections that Section 1557 currently provides and has provided since enactment.²³⁶

²³⁵ The comments addressed in this section pertain to comments related to the implementation date of § 92.207. OCR also received comments requesting a delayed effective date for the rule in general, which are discussed *supra* under § 92.1 of this preamble.

²³⁶ We note that issuers have been provided notice that they are subject to Section 1557 in other Departmental regulations (HHS's Notice of Benefit and Payment Parameters for 2017, Final Rule, 80 FR 12204, 12312 (Mar. 8, 2016); HHS's Notice of Benefit and Payment Parameters for 2017, Proposed

That said, we recognize that some covered entities will have to make changes to their health insurance coverage or other health coverage to bring that coverage into compliance with this final rule. We are sensitive to the difficulties that making changes in the middle of a plan year could pose for some covered entities and are committed to working with covered entities to ensure that they can comply with the final rule without causing excessive disruption for the current plan year.

Consequently, to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

Comment: Several commenters representing issuers and large employers recommended that the rule exempt from Section 1557 benefits that constitute excepted benefits under section 2791(c) of the Public Health Service Act (codified at 42 U.S.C. 300gg–91(c)), which generally are exempt from market reforms under the ACA and HIPAA portability requirements. Excepted benefits include, but are not limited to: limited scope dental and vision plans; coverage only for a specified disease or illness; and Medicare supplemental health insurance (also known as Medigap).²³⁷ Commenters suggested that being excepted from the ACA market reforms and HIPAA portability requirements should result in exemption from Section 1557. Others stated that covering excepted benefits under the rule would serve as a disincentive to employers to provide these benefits due to increased litigation risk.

Response: We are not exempting benefits excepted from ACA market reforms and HIPAA portability requirements from the final rule. If an issuer providing these benefits receives Federal financial assistance and is principally engaged in providing health benefits, all of its operations will be covered by the rule; if it is not principally engaged, we will apply the rule to its federally funded health

Rule, 80 FR 75488, 75553 (Dec. 2, 2015); HHS's Notice of Benefit and Payment Parameters for 2016, Final Rule, 80 FR 10750, 10823 (Feb. 27, 2015)).

²³⁷ 42 U.S.C. 300gg–91(c).

²³³ See *supra* discussion on deeming compliance with other laws in the General Comments section.

²³⁴ 78 FR at 33168; U.S. Dep't of Health & Human Servs., Center for Medicare & Medicaid Servs., Affordable Care Act Implementation FAQs Set 2, Q5, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html (last visited May 4, 2016).

programs and activities. Many of the benefits excepted from the ACA market reforms and HIPAA portability rules will meet the definition of “health program and activity.”²³⁸

Nothing in the text of Section 1557 limits its coverage only to health programs and activities created or regulated by other provisions of the ACA. Indeed, Section 1557’s incorporation of the four civil rights laws to which it refers, as those laws were amended by the CRRRA, conclusively suggests otherwise. Moreover, Title VI, Section 504, and the Age Act independently apply to these benefits,²³⁹ and other civil rights laws, such as Title VII, apply to these benefits when they are provided as a fringe benefit of employment by employers covered by that law.

There are several statutorily-defined categories of excepted benefits that are exempt from the ACA market reforms and HIPAA portability requirements if certain conditions are satisfied, such as when medical benefits are incidental or secondary to other insurance benefits, when the benefits are limited in scope or supplemental, or when the benefits are provided as independent, non-coordinated benefits.²⁴⁰ Excepted benefits do not provide comprehensive medical coverage and do not satisfy the individual or employer responsibility provisions under the ACA. But these characteristics do not justify an exemption from the requirements of Section 1557, which reflects the fundamental policy that entities that operate health programs and activities, any part of which receives Federal funds, cannot use those funds to discriminate—however broad or narrow the scope of those health programs and activities may be.

Comment: Some commenters requested that OCR address a number of issues that are not within the purview of OCR or Section 1557, including the scope of essential health benefit coverage and establishing minimum network adequacy requirements.

Response: OCR appreciates the commenters’ suggestions, but the commenters’ requests are beyond the scope of this regulation. CMS is statutorily responsible for establishing and regulating the scope of essential health benefits and network adequacy requirements for health insurance

issuers. Absent any allegation that a covered entity has discriminated on a basis prohibited by Section 1557, OCR lacks authority to address the terms of these CMS regulations.

Comment: Several commenters asked that OCR exercise more stringent and consistent oversight over consumer access to a wide range of specialists and subspecialists. Commenters pointed out that many qualified health plans in the MarketplaceSM offer network-based plans, and enrollee cost-sharing can be substantially lower when care is delivered by an in-network provider. The commenters expressed concern that some issuers appear to systematically exclude from their provider networks high-cost providers or those in certain high-cost specialties. The commenters suggested that narrow networks could potentially be discriminatory if they deprive patients of reasonable access to a specialty provider or if they discourage enrollment by individuals with specific health needs.

Response: OCR agrees that provider networks with a wide range of specialists and subspecialists are beneficial for consumers and appreciates the concerns expressed about the effect of the exclusion of certain specialists from an issuer’s network. We clarify, however, that it is beyond the scope of this regulation to establish uniform or minimum network adequacy standards. Qualified health plan issuers are subject to network adequacy requirements under CMS regulations.²⁴¹

Comment: Some commenters asked OCR to clarify that issuers cannot discriminate against providers based on a provider’s protected status. That is, these commenters recommended that OCR make clear that Section 1557’s prohibition of discrimination is not limited in scope to the health care consumer and extends to other entities that may be engaged in health programs and activities.

Response: OCR clarifies that covered entities providing or administering health-related insurance or other health-related coverage may not discriminate against or exclude health care providers they contract with on the basis of the provider’s race, color, national origin, sex, age, or disability. OCR reminds covered entities that they may have obligations under other Federal laws prohibiting discrimination against providers²⁴² or against employees.²⁴³

Comment: A few commenters asked OCR to amend § 92.207(a) so that it more clearly describes the various activities that a covered entity may perform that are considered “administering” health-related insurance or other health-related coverage. Specifically, these commenters asked that OCR add language to § 92.207(a) explaining that administering health-related insurance or other health-related coverage may include claims processing, rental of a provider network, designing plan benefits or policies, drafting plan documents, processing or adjudicating appeals, administering disease management services, and pharmacy benefit management.

Response: We appreciate the commenters’ suggestion, but we believe the regulatory text is clear as written and does not require further clarification. The term “administering” is broad enough to encapsulate a variety of activities related to the administration of health-related insurance or other health-related coverage.

Comment: We received a number of comments related to the proper handling of claims alleging discrimination in employee health benefit plans that are covered by both this rule and other Federal laws and regulations. For example, several commenters recommended that the rule not apply to the services of third party administrators providing administrative services to self-insured group health plans. These commenters asserted that Congress did not intend for third party administrators to be covered by Section 1557 and asserted that third party administrators do not design plans, are not responsible for determining the benefits covered under the plan, and are required by ERISA²⁴⁴ to administer plans as they are written. Commenters also asserted that coverage of third party administrators would indirectly subject self-insured group health plans to Section 1557 and create an unlevel playing field between third party administrators operated by issuers that receive Federal financial assistance and those that do not, thereby creating a disincentive for self-insured group health plans to contract with third party administrators that participate as issuers in the MarketplaceSM and a resulting

²³⁸ We note that non-health-related excepted benefits would be covered under the rule if offered by a covered entity that is principally engaged in providing health care or health coverage.

²³⁹ Title IX applies to these benefits to the extent they are provided in connection with federally funded educational programs or activities.

²⁴⁰ 42 U.S.C. 300gg–91(c).

²⁴¹ 45 CFR 156.230.

²⁴² See, e.g., 42 U.S.C. 300gg–5(a); 42 CFR 422.205(a).

²⁴³ See, e.g., Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e–2000e–17), the ADA (42

U.S.C. 12101 *et seq.*), the Age Discrimination in Employment Act (29 U.S.C. 621–634); Executive Order 11246 (30 FR 12319, 12935, 3 CFR, 1964–1965, as amended), Section 503 of the Rehabilitation Act of 1973 (29 U.S.C. Sec. 793), and the Vietnam Veterans’ Readjustment Assistance Act of 1974 (38 U.S.C. Sec. 4212).

²⁴⁴ 29 U.S.C. 1001 *et seq.*

disincentive for issuers to offer qualified health plans on the MarketplaceSM. These commenters also emphasized that self-insured group health plans are already subject to extensive Federal regulation under ERISA.

Some commenters representing issuers and larger employers also objected to language in footnote 73²⁴⁵ in the preamble of the proposed rule stating that when an entity that acts as a third party administrator is legally separate from the issuer that receives Federal financial assistance, we will engage in a case-by-case analysis to determine whether the third party administrator is subject to the rule. These commenters stated that the rule should never extend beyond the legal entity that receives the Federal financial assistance.

Response: We are not excluding third party administrator services from the final rule; however, we are adopting specific procedures to govern the processing of complaints against third party administrators.

Third party administrator services are undeniably a health program or activity, as they involve the administration of health services. Under the final rule, if an entity that receives Federal financial assistance is principally engaged in providing or administering health services, health insurance coverage, or other health coverage, then, consistent with the approach taken under the civil rights laws referenced in Section 1557 and under the CRRA, as discussed *supra*,²⁴⁶ all of its operations are covered. Thus, if an issuer that receives Federal financial assistance is principally engaged in providing health insurance and also provides third party administrator services, there is no principled basis on which to exclude the law's application to the third party administrator services or to treat them differently from other entities and services covered by the rule.

Commenters' assertion that employers or group health plans may have an incentive to contract with third party administrators that are operated by entities that do not receive Federal financial assistance does not justify exempting third party administrator services from the rule. Commenters' rationale would undermine the application of all of the civil rights laws that attach obligations to the receipt of Federal financial assistance; if any competitive disparity exists here, it is no different than in other types of

businesses in which some entities receive Federal financial assistance and others do not.

Moreover, the fact that third party administrators are governed by other Federal laws such as ERISA is not a reason to exempt them from Section 1557. ERISA itself explicitly preserves the independent operation of civil rights laws, by providing that nothing in ERISA "shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States . . . or any rule or regulation issued under any such law."²⁴⁷ And in any event, the fact that entities are subject to regulation under other Federal statutory schemes adopted for other purposes does not justify insulating them from the obligation to comply with civil rights requirements.²⁴⁸

Commenters expressed a number of concerns related to the relationship between third party administrators and the employers whose self-insured group health plans they administer. OCR clarifies here that, contrary to the understanding of some commenters, Section 1557's coverage of a third party administrator under the rule does *not* extend to the coverage of an employer providing a group health plan that is being administered by the third party administrator. The rule addresses employer liability separately from that of issuers that receive Federal financial assistance;²⁴⁹ under Section 1557, an employer is liable for discrimination in its employee health benefit programs only if the employer is principally engaged in health services, health insurance coverage, or other health coverage, or otherwise satisfies one of the criteria set forth in § 92.208. Whether an employer's group health plan is administered by a third party administrator that is a covered entity is not relevant in this analysis.

In response to commenters' arguments on this point, however, OCR recognizes that third party administrators are generally not responsible for the benefit design of the self-insured plans they administer and that ERISA (and likely the contracts into which third party administrators enter with the plan sponsors) requires plans to be administered consistent with their terms.²⁵⁰ Thus, if a plan has a discriminatory benefit design under Section 1557, a third party administrator could be held responsible

for plan features over which it has no control.

Based on these comments, OCR is adjusting the way in which it will process claims that involve alleged discrimination in self-insured group health plans administered by third party administrators that are covered entities. Fundamentally, OCR will determine whether responsibility for the decision or other action alleged to be discriminatory rests with the employer or with the third party administrator. Thus, where the alleged discrimination is related to the administration of the plan by a third party administrator that is a covered entity, OCR will process the complaint against the third party administrator because it is that entity that is responsible for the decision or other action being challenged in the complaint. Where, for example, a third party administrator denies a claim because the individual's last name suggests that she is of a certain national origin or threatens to expose an employee's transgender or disability status to the employee's employer, OCR will proceed against the third party administrator as the decision-making entity. Where, by contrast, the alleged discrimination relates to the benefit design of a self-insured plan—for example, where a plan excludes coverage for all health services related to gender transition—and where OCR has jurisdiction over a claim against an employer under Section 1557 because the employer falls under one of the categories in § 92.208, OCR will typically address the complaint against that employer.

As part of its enforcement authority, OCR may refer matters to other Federal agencies with jurisdiction over the entity. Where, for example, OCR lacks jurisdiction over an employer responsible for benefit design, OCR typically will refer or transfer the matter to the EEOC and allow that agency to address the matter. The EEOC has informed OCR that, provided the filing meets the requirements for an EEOC charge, the date a complaint was filed with OCR will be deemed the date it was filed with the EEOC (although any subsequent denial of a renewed coverage request could be separately challenged by a timely complaint).

This approach is consistent with our efforts to ensure coordination with other Federal agencies that can also exercise jurisdiction over the subject of a particular complaint. Thus, we will also coordinate with the Office of Personnel Management (OPM) in the handling of claims alleging discrimination in the Federal Employees Health Benefits (FEHB) Program. OPM is charged by

²⁴⁵ 80 FR at 54189 n.73.

²⁴⁶ See *supra* discussion of the CRRA under the discussion of "health program or activity" under § 92.4.

²⁴⁷ 29 U.S.C. 1144(d).

²⁴⁸ See *supra* discussion on deeming compliance with other laws in the General Comments section.

²⁴⁹ See § 92.208 and discussion of § 92.208 *infra*.

²⁵⁰ See 29 U.S.C. 1104(a)(1)(D).

Federal statute²⁵¹ with offering FEHB plans as a fringe benefit of Federal employment and, in that role, approves benefit designs and premium rates, sets rules generally applicable to FEHB carriers, adjudicates and orders payment of disputed health claims, and adjusts policies as necessary to ensure compliance with nondiscrimination standards. As a result, OCR will refer to OPM complaints that allege discrimination in the FEHB Program where OPM is the entity with decision-making authority over the challenged action; OPM will treat these claims as complaints filed against OPM and will seek relief comparable to that available were these claims to be processed by OCR under Section 1557.

In response to the comments requesting additional clarification on footnote 73 in the proposed rule, we reiterate that we will engage in a case-by-case inquiry to evaluate whether a third party administrator is appropriately subject to Section 1557 as a recipient in situations in which the third party administrator is legally separate from an issuer that receives Federal financial assistance for its insurance plans. This analysis will rely on principles developed in longstanding civil rights case law, such as the degree of common ownership and control between the two entities,²⁵² and will also examine whether the purpose of the legal separation is a subterfuge for discrimination—that is, intended to allow the entity to continue to administer discriminatory health-related insurance or other health-related coverage.²⁵³ But we note that a third party administrator is unlikely to be covered by this final rule where it is a legal entity that is truly independent of an issuer's other, federally funded, activities.

Comment: Commenters requested clarification on OCR's approach when evaluating whether a prohibited discriminatory action occurred under § 92.207(b).

Response: We clarify that OCR's approach in applying basic nondiscrimination principles, as discussed in the proposed rule under § 92.207(b)(5)²⁵⁴ relating to coverage for specific health services related to gender transition, is the same general approach that OCR will take when evaluating denials or limitations of coverage for

other types of health services. In other words, OCR will evaluate whether a covered entity utilized, in a nondiscriminatory manner, a neutral rule or principle when deciding to adopt the design feature or take the challenged action or whether the reason for its coverage decision is a pretext for discrimination. For example, if a plan limits or denies coverage for certain services or treatment for a specific condition, OCR will evaluate whether coverage for the same or a similar service or treatment is available to individuals outside of that protected class or those with different health conditions and will evaluate the reasons for any differences in coverage. Covered entities will be expected to provide a neutral, nondiscriminatory reason for the denial or limitation that is not a pretext for discrimination.

Comment: One commenter asked OCR to clarify that targeted marketing practices designed to reach certain populations to increase enrollment, such as specific segments of those who are uninsured or underserved, are not considered discriminatory. This commenter pointed out that some issuers sometimes launch targeted campaigns to reach a high number of uninsured in their service areas. In so doing, issuers may study the profile of uninsured populations, and based on the results of that study, may concentrate their marketing efforts on certain demographic groups that are disproportionately uninsured or underserved. The commenter cited a Gallup Poll that indicated that roughly one-third of Hispanics remain uninsured, which the commenter stated creates a particular need for issuers to help educate and expand coverage for this community. The commenter sought reassurance that OCR will not consider it discriminatory to target enrollment efforts where they will make the most difference.

Response: Congress intended the ACA to help uninsured and underserved populations gain access to care. Nothing in this regulation is intended to limit targeted outreach efforts to reach underserved racial or ethnic populations or other underserved populations. Indeed, it is OCR's intention that this regulation will increase access for uninsured and underserved populations, much as other Departmental regulations implementing the ACA have strived to do.²⁵⁵

Comment: Several commenters recommended that we define “marketing practices” in the regulatory text of § 92.207(b)(2). These commenters suggested that the inclusion of a precise definition for “marketing practices” would serve to clarify the scope of § 92.207(b)(2).

Response: We decline to define “marketing practices” in the final rule because to do so would be overly prescriptive. We emphasize, however, that we intend to interpret the term “marketing practices” broadly; such practices would include, for example, any activity of a covered entity that is designed to encourage individuals to participate or enroll in the covered entity's programs or services or to discourage them from doing so, and activities that steer or attempt to steer individuals towards or away from a particular plan or certain types of plans. We remind covered entities that other Departmental regulations address marketing practices,²⁵⁶ and covered entities are obligated to comply with all applicable Federal and State laws regarding such practices.

Comment: Many commenters recommended that we define “benefit design” in the regulatory text of the final rule. These commenters suggested that the inclusion of a precise definition of “benefit design” would serve to clarify the scope of § 92.207(b)(2). In addition, numerous commenters requested that we codify or provide examples of benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability. A number of commenters urged OCR to consider specific types of benefit designs as constituting per se discrimination under § 92.207(b)(2) of the final rule.

Response: We appreciate commenters' requests for guidance and clarification regarding potentially discriminatory benefit designs and suggestions for scenarios that constitute per se discrimination. However, we decline to

155.210(e)(8) to require Navigators to provide targeted assistance to serve underserved or vulnerable populations).

²⁵⁶ 45 CFR 156.225(b) (prohibiting qualified health plans from employing marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs); 45 CFR 147.104(e) (prohibiting a health insurance issuer from employing marketing practices or benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, gender identity, sexual orientation, expected length of life, degree of medical dependency, quality of life, or other health conditions); 42 CFR 422.2260–422.2615 (establishing Part D marketing requirements).

²⁵¹ 5 U.S.C. 8901 *et seq.*

²⁵² See, e.g., *Papa v. Katy Indus., Inc.*, 166 F.3d 937, 939 (7th Cir. 1999), *cert. denied*, 528 U.S. 1019 (1999) (ADA, ADEA); *Arrowsmith v. Shelbourne, Inc.*, 69 F.3d 1235, 1240–42 (2d Cir. 1995) (Title VII).

²⁵³ *Papa v. Katy Indus., Inc.*, 166 F.3d at 941.

²⁵⁴ 80 FR at 54190.

²⁵⁵ See, e.g., 45 CFR 155.210(b)(2)(i) (requiring Exchanges to develop and publically disseminate Navigator training standards that ensures expertise in the needs of underserved and vulnerable populations); 81 FR 12204, 12338 (Mar. 8, 2016) (establishing new requirement at 45 CFR

define “benefit design” in the final rule because to do so would be overly prescriptive.²⁵⁷ We also decline to codify examples of discriminatory benefit designs because determining whether a particular benefit design results in discrimination will be a fact-specific inquiry that OCR will conduct through its enforcement of Section 1557. For the same reason, we avoid characterizing specific benefit design practices as per se discriminatory in the final rule.²⁵⁸

OCR will analyze whether a design feature is discriminatory on a case-by-case basis using the framework discussed above. We reiterate that our determination of whether a practice constitutes discrimination will depend on our careful analysis of the facts and circumstances of a given scenario. OCR recognizes that covered entities have discretion in developing benefit designs and determining what specific health services will be covered in their health insurance coverage or other health coverage. The final rule does not prevent covered entities from utilizing reasonable medical management techniques; nor does it require covered entities to cover any particular procedure or treatment. It also does not preclude a covered entity from applying neutral, nondiscriminatory standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner. The rule prohibits a covered entity from employing benefit design or program

administration practices that operate in a discriminatory manner.

Comment: We received a number of comments requesting that OCR add language to § 92.207(b) clarifying that categorical exclusions of certain conditions, such as coverage related to developmental disabilities or maternity care, are prohibited.

Response: While categorical exclusions of all coverage related to certain conditions could raise significant compliance concerns under Section 1557, OCR believes that existing regulatory language is sufficient to address this scenario. For example, the law has long recognized that discrimination based on pregnancy is a form of sex discrimination,²⁵⁹ and OCR has interpreted Section 1557 in the same manner by defining the term “on the basis of sex” in this regulation to include “discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions.” As a result, it is unnecessary to add language in response to commenters’ concerns.

We note that some products known as excepted benefits, which are subject to this final rule as discussed *supra*, provide limited scope benefits or coverage only for a specified disease or illness.²⁶⁰ It would not be discriminatory for such products to include exclusions of coverage for conditions that are outside the scope of the benefits provided in those products. Accordingly, the purpose and scope of the coverage provided under health-related insurance or health-related coverage are factors that OCR will consider in determining whether an exclusion of all coverage for a certain condition is discriminatory under this final rule.

Comment: In light of OCR’s statement in the preamble to the proposed rule that “[t]he proposed rule does not require plans to cover any particular benefit or service, but a covered entity cannot have a coverage policy that operates in a discriminatory manner,”²⁶¹ a few commenters asked OCR to clarify that the solution to a potentially discriminatory benefit

design could be addition of coverage for a benefit or service.

Response: OCR agrees that the solution to a potentially discriminatory benefit design could be coverage, or added coverage, of a benefit or service.

Comment: The proposed rule invited comment as to whether the approach of § 92.207(b)(1)–(5) is over- or under-inclusive of the types of potentially discriminatory claim denials experienced by transgender individuals in their attempts to access coverage and care, as well as on how nondiscrimination principles apply in this context.²⁶² Many commenters supported OCR’s approach in prohibiting a range of practices that discriminate against transgender individuals by denying or limiting coverage for medically necessary and medically appropriate health services. Numerous commenters asserted that the protections at § 92.207(b)(3)–(5) are vital to ensuring that transgender individuals are able to access the health coverage and care they need and urged OCR to preserve these provisions in the final rule.

For instance, many commenters strongly supported the proposed rule’s prohibition against categorical or automatic exclusions of coverage for all health services related to gender transition. These commenters further supported the proposed rule’s prohibition against otherwise denying or limiting coverage, or denying a claim, for health services related to gender transition if such a denial or limitation results in discrimination against a transgender individual. These commenters expressed hope that these prohibitions will serve to eliminate the significant barriers that transgender individuals have faced in accessing coverage for transition-related care, such as counseling, hormone therapy, and surgical procedures that they said had previously been denied to them because they have been viewed as cosmetic or experimental. Many commenters also favored the prohibition against denying, limiting, or otherwise restricting coverage for health services that are ordinarily or exclusively available to individuals of one sex based on an individual’s gender identity. Commenters indicated that the proposed rule’s protections will help to resolve various health care disparities suffered by transgender individuals.

Several commenters, however, opposed the protections that the proposed rule affords to transgender individuals. Some commenters suggested that covered entities should

²⁵⁷ We note that “benefit design” is a term of art used in other Departmental and Federal regulations governing the private health insurance industry. See e.g., 42 CFR 422.100(f)(3); 45 CFR 156.225(b); 45 CFR 147.104(e); 29 CFR 2510.3–40(c)(1)(iv)(A).

²⁵⁸ CMS has identified benefit design features that might be discriminatory. For example, placing most or all prescription medications that are used to treat a specific condition on the highest cost formulary tiers (U.S. Dep’t of Health & Human Servs., Centers for Medicare & Medicare Servs., Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters Rule, (Final Rule), 80 FR 10750, 10822 (Feb. 27, 2015); U.S. Dep’t of Health & Human Servs., Centers for Medicare and Medicaid Servs., Final 2016 Letter to Issuers in the Federally-facilitated Marketplace, 37 (Feb. 20, 2015)); applying age limits to services that have been found clinically effective at all ages (80 FR at 10822 (Feb. 27, 2015); Final 2016 Letter to Issuers in the Federally-facilitated Marketplace, 36–37 (Feb. 20, 2015)); and requiring prior authorization and/or step therapy for most or all medications in drug classes such as anti-HIV protease inhibitors, and/or immune suppressants regardless of medical evidence (Centers for Medicare and Medicaid Servs., Qualified Health Plan Master Review Tool, Non-Discrimination in Benefit Design (2017), https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Master-Review-Tool_v1-1_03302016.zip (open “Master Review Tool_2017v1.0.xlsm” document; then open “Non-Discrimination Guidance” tab)).

²⁵⁹ Title VII prohibits discrimination in employment practices “because of sex,” 42 U.S.C. 2000e–2(a), which is defined to include “because of or on the basis of pregnancy, childbirth, or related medical conditions. . . .” 42 U.S.C. 2000e(k); *Newport News Shipbuilding & Dry Dock Co. v. EEOC*, 462 U.S. 669, 684 (1983) (“discrimination based on a woman’s pregnancy is, on its face, discrimination because of her sex.”).

²⁶⁰ 42 U.S.C. 300gg–91(c).

²⁶¹ 80 FR at 54189.

²⁶² 80 FR at 54191.

be permitted to categorically exclude coverage for transition-related health services based on moral or religious convictions that an individual's biological sex, or sex assigned at birth, should not be altered. Other commenters suggested that OCR is exceeding its legal authority by addressing covered entities' provision of coverage to transgender individuals because discrimination based on gender identity should not be recognized as a form of sex discrimination.

Response: We agree with the commenters who expressed their general support of the protections for transgender individuals afforded by the provisions at § 92.207(b)(3)–(5), and therefore we are keeping the provisions as proposed. We believe that it is important to ensure that civil rights protections are extended to transgender individuals to afford them equal access to health coverage, including for health services related to gender transition. As we stated in the preamble to the proposed rule, the across-the-board categorization of all transition-related treatment, for example as experimental, is outdated and not based on current standards of care.²⁶³

Further, we disagree with commenters who asserted that sex-based discrimination does not include discrimination based on gender identity. As discussed previously,²⁶⁴ OCR's definition of discrimination "on the basis of sex" is consistent with the well-accepted interpretations of other Federal agencies and courts. Further, as previously noted in this preamble,²⁶⁵ we decline to adopt a blanket religious exemption in the final rule as any religious concerns are appropriately addressed pursuant to pre-existing laws such as RFRA and provider conscience laws.

Comment: A significant number of commenters recommended that OCR revise the language in § 92.207(b)(4) that

prohibits categorical exclusions or limitations of "all health services related to gender transition" to remove the word "all," and proposed modifications to § 92.207(b)(3)–(5) relating to the medical necessity or medical appropriateness of coverage for health services related to gender transition and sex-specific services. Other commenters, concerned that the rule may be too broadly interpreted, requested clarification as to when gender transition services or sex-specific services must be provided and recommended that the rule specify that such health services are to be provided only when medically necessary or medically appropriate. These commenters also requested that OCR clarify that the rule's intent is not to require covered entities to cover elective services or mandate that it cover certain services. Conversely, other commenters specifically requested that the rule clarify that covered entities cannot deny medically necessary services for gender transition-related care because such treatment is medically necessary for transgender individuals. Further, some commenters suggested that covered entities must provide coverage for procedures or services to treat gender dysphoria or associated with gender transition when substantially similar procedures or services are covered for other conditions. For example, commenters observed that a hysterectomy to treat gender dysphoria is substantially similar to a hysterectomy performed for cancer treatment or prevention in a cisgender woman (*i.e.*, a woman whose gender identity is consistent with her sex assigned at birth).

Response: OCR appreciates the array of comments provided but does not believe it is necessary to revise the regulatory text. As noted in the preamble to the proposed rule, we will evaluate whether a particular exclusion is discriminatory based on the application of longstanding nondiscrimination principles to the facts of the particular plan or coverage. Under these principles, issuers are not required to cover all medically necessary services. Moreover, we do not affirmatively require covered entities to cover any particular treatment, as long as the basis for exclusion is evidence-based and nondiscriminatory.

Thus, we reject commenters' suggestion that the rule require covered entities to provide coverage for all medically necessary health services related to gender transition regardless of the scope of their coverage for other conditions.

At the same time, the rule does require that a covered entity apply the same neutral, nondiscriminatory criteria that it uses for other conditions when the coverage determination is related to gender transition. Thus, if a covered entity covers certain types of elective procedures that are beyond those strictly identified as medically necessary or appropriate, it must apply the same standards to its coverage of comparable procedures related to gender transition. As a result, we decline to limit application of the rule by specifying that coverage for the health services addressed in § 92.207(b)(3)–(5) must be provided *only* when the services are medically necessary or medically appropriate.

With regard to § 92.207(b)(3), we recognize that not every health service that is typically or exclusively provided to individuals of one sex will be a health service that is appropriately provided to a transgender individual. Nothing in the rule would, for example, require an issuer to cover a traditional prostate exam for an individual who does not have a prostate, regardless of that individual's gender identity. However, the issuer must cover the health services that are appropriately provided to an individual by applying the same terms and conditions, regardless of an individual's sex assigned at birth, gender identity, or recorded gender.

We also clarify that the prohibition in § 92.207(b)(4) on categorically limiting coverage for all health services related to gender transition is intended to prevent issuers from placing categorical, arbitrary limitations or restrictions on coverage for all gender transition-related services, such as by singling out services related to gender transition for higher co-pays; it is not intended to prevent issuers from placing nondiscriminatory limitations or restrictions on coverage under the plan. We have revised the language of the provision to clarify that intent.

Comment: Some commenters requested that the final rule define "health services related to gender transition."

Response: We decline to include a definition of "health services related to gender transition." OCR intends to interpret these services broadly and recognizes that health services related to gender transition may change as standards of medical care continue to evolve.

The range of transition-related services, which includes treatment for gender dysphoria, is not limited to surgical treatments and may include, but is not limited to, services such as

²⁶³ 80 FR at 54189. See *e.g.*, World Professional Association for Transgender Health (WPATH), *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People* (7th ed. 2011), [http://www.wpath.org/uploaded_files/140/files/Standards Of Care, V7 Full Book.pdf](http://www.wpath.org/uploaded_files/140/files/Standards%20of%20Care_V7_Full_Book.pdf); Institute of Medicine of the National Academies, *The Health of Lesbian, Gay, Bisexual and Transgender People: Building a Foundation for Better Understanding* (2011); www.nationalacademies.org/hmd/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx. See also U.S. Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Division NCD 140.3, Docket No. A-13-87, Decision No. 2576, 22-24 (May 30, 2014), <http://www.hhs.gov/dab/decisions/dabdecisions/dab2576.pdf>.

²⁶⁴ See *supra* discussion of the definition "on the basis of sex" under § 92.4.

²⁶⁵ See *supra* discussion on including a religious exemption under § 92.2.

hormone therapy and psychotherapy, which may occur over the lifetime of the individual. We believe the flexibility of the general language in the final rule best serves transgender individuals and covered entities.

Comment: Several commenters expressed concern that some issuers do not yet have the technological capability to avoid initial denials of coverage for sex-specific services for transgender individuals due to their computer systems flagging a mismatch between the gender of the individual identified at enrollment and the billing code associated with the biological sex that typically receives the health service. The commenters explained that issuers' computer systems accommodate only binary gender billing codes (e.g., "male" or "female") and cannot accommodate descriptions of an enrollee's gender identity. Further, commenters observed that the Health Insurance MarketplaceSM enrollment application available through *HealthCare.gov* permits applicants to identify themselves only as male or female and does not currently allow applicants to denote their gender identity. These commenters noted that, as a result, qualified health plan issuers receive incomplete information about an enrollee's gender identity and biological sex. Moreover, these commenters requested that OCR clarify that an initial denial of a transgender enrollee's claim due to the discrepancy between the enrollee's recorded gender and the sex with which the health service is generally associated does not constitute discrimination if the enrollee is able to reverse the denial through an internal appeals process.

Response: As we indicated in the proposed rule,²⁶⁶ we recognize that some issuers use computer systems that accommodate only binary gender billing codes that flag a gender mismatch for coverage of certain sex-specific services. We noted that such flagging, by itself, would not be impermissible if it does not result in a delay or denial of services or a claim for services. We reject, however, the commenters' suggestion that an initial denial of a transgender enrollee's claim should never be considered discriminatory as long as the enrollee is able to correct the denial through the internal appeals process. Requiring transgender enrollees to repeatedly go through the internal appeals process to obtain coverage for certain services would subject these enrollees to a burdensome process that

is likely to delay their receipt of coverage.

Moreover, there are available interim methods for correcting initial coverage denials due to computer systems flagging a gender mismatch that issuers can use as their computer systems are updated. For instance, we understand that current billing code practices include general billing code modifiers that are used to identify situations in which issuers need to evaluate further claims that might otherwise be automatically rejected. As a result, issuers could advise health care providers to submit an existing billing code modifier along with a claim for sex-specific services for a transgender patient to flag the billing for the issuer's further review.²⁶⁷ Issuers are free to develop another method of processing claims for sex-specific services by transgender individuals as long as the process is not overly burdensome and provides timely access to care. We note that commenters have raised concerns about the Health Insurance MarketplaceSM enrollment application and will address these concerns as appropriate.

Comment: One commenter recommended that we extend a safe harbor protection to issuers who demonstrate their good faith compliance with § 92.207(b)(3) for the time period during which they update their computer systems and operations to prevent inappropriate denials of coverage for sex-specific services for transgender enrollees.

Response: While we reject the commenter's recommendation of a safe harbor protection, OCR is willing to work with issuers to help identify potential interim solutions and to come into compliance.

Comment: One commenter requested clarification regarding whether an issuer may require transgender enrollees to provide additional information related to their biological sex to enable the issuer to override inappropriate denials of coverage for sex-specific health services. Another commenter inquired as to whether an issuer is permitted to request information about an applicant's

biological sex on an insurance application form.

Response: We understand that, in some instances, a covered entity may need to ask transgender enrollees for additional information, including information related to their biological sex or sex assigned at birth, to facilitate overriding denials of coverage for sex-specific health services due to gender billing code mismatches in their computer systems. We clarify in this preamble that a covered entity is permitted to ask transgender enrollees to provide such additional information, as long as the covered entity does not unduly burden enrollees or make unreasonable inquiries that serve to delay their receipt of coverage. In addition, we clarify that it is permissible for a covered entity to request information about the biological sex of the applicant on an insurance application form to assist the covered entity in identifying the medical appropriateness of sex-specific health services, as long as the information requested is not used in a discriminatory manner, and the collection and use of the information is otherwise lawful and complies with applicable HIPAA privacy requirements.

Comment: Many commenters recommended revisions to § 92.207(d), which provides that nothing in this section is intended to determine, or restrict a covered entity from determining, whether a particular health service is medically necessary or otherwise meets applicable coverage requirements in any individual case. Some commenters requested that we revise this provision to ensure that a covered entity does not use criteria that lead to a discriminatory result in its medical necessity or coverage determinations. For example, some commenters suggested that we require covered entities to use certain treatment guidelines when determining medical necessity or coverage for transgender-related health services, such as those published by the WPATH. Conversely, other commenters expressed concern that Section 1557 may unduly restrict a covered entity's ability to evaluate medical necessity in its coverage determinations and requested clarification that covered entities are permitted to require certain treatment, such as mental health services for gender dysphoria, as part of their medical necessity or coverage determinations.

Response: We appreciate the concerns raised by commenters, but we are maintaining the language in § 92.207(d) without revision. OCR will not second-guess a covered entity's neutral

²⁶⁷ The Medicare program already directs providers to use this approach. See Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., Medicare Claims Processing Manual, Chapter 32, Transmittal 240: Special Instructions for Certain Claims with a Gender/Procedure Conflict (last revised Jan. 20, 2015), (directing providers to use an approved national billing code for sex-specific services for transgender patients to alert the contractor that it is not an error and to allow the claim to continue with normal processing), [https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/clm104c32.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf).

²⁶⁶ 80 FR at 54189 n.75.

nondiscriminatory application of evidence-based criteria used to make medical necessity or coverage determinations. Therefore, we refrain from adding any regulatory text that establishes or limits the criteria that covered entities may utilize when determining whether a health service is medically necessary or otherwise meets applicable coverage requirements. Nevertheless, we caution covered entities that, although § 92.207(d) does not dictate the criteria that a covered entity must use, a covered entity must use a nondiscriminatory process to determine whether a particular health service is medically necessary or otherwise meets applicable coverage requirements.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.207 with minor technical revisions for clarity, to make our intent clear, and to ensure consistency with other parts of the final rule. We are making technical corrections to paragraphs (b)(1), (b)(3) and (b)(5) to add the word “coverage” where appropriate to reconcile with other parts of the rule. In (b)(1), we are making two modifications to the language. We are reconciling the usage of “health-related insurance” and “other health-related coverage” by adding “related” to those terms in (b)(1). We are also removing reference to “enrollees” as it unintentionally limited application of the paragraph. In (b)(2), we are replacing text that prohibited employing discriminatory marketing practices or benefit designs with text that prohibits having or implementing discriminatory marketing practices or benefit designs to clarify our intent that both having and applying discriminatory marketing practices and benefit design are prohibited. This clarification does not substantively modify the prohibition set forth in the proposed rule. In (b)(3), we are adding the words “to a transgender individual” for clarity, and are deleting the words “by the plan or issuer” for consistency with other parts of the rule. In (b)(4), we are revising the language to be clear that our intent was to prohibit categorical exclusions or limitations in both benefit design and administration; thus, we are replacing language prohibiting categorical or automatic exclusions or limitations of coverage with language that prohibits having or implementing a categorical exclusion or limitation of coverage. This clarification does not substantively modify the prohibition set forth in the proposed rule. In (b)(5), we also are revising the

description of the prohibited actions to reconcile the language with other paragraphs in § 92.207(b).

Employer Liability for Discrimination in Employee Health Benefit Programs (§ 92.208)

In § 92.208, we proposed to address the application of Section 1557 to employers that offer health benefit programs to their employees. Under our proposed approach, where an entity that receives Federal financial assistance provides an employee health benefit program to its employees, it will be liable for discrimination in that employee health benefit program under this part only in three defined circumstances.²⁶⁸ In paragraph (a), we proposed that where an employer is principally engaged in providing or administering health services or health coverage and receives Federal financial assistance, the employer would be subject to Section 1557 in its provision or administration of employee health benefit programs to its employees. Thus, if a hospital provides health benefits to its employees, it will be covered by Section 1557 not only for the services it offers to its patients or other beneficiaries but also for the health benefits it provides to its employees.²⁶⁹

In paragraph (b), we proposed that where an entity receives Federal financial assistance the primary objective of which is to fund an employee health benefit program, that entity’s provision or administration of the health benefit program will be covered by Section 1557 regardless of the business in which the entity is engaged.

In paragraph (c), we proposed that an employer that is not principally engaged in providing or administering health services or health insurance coverage, but that operates a health program or activity (that is not an employee health benefit program) that receives Federal financial assistance, will be covered for its provision or administration of an

²⁶⁸ As reflected in § 92.101(a)(2) and as discussed in the preamble of the proposed rule, 80 FR at 54180, except as provided here, the proposed rule does not generally apply to discrimination by a covered entity against its own employees. Thus, the rule does not generally extend to hiring, firing, promotions, or terms and conditions of employment outside of those identified in § 92.208; such claims would continue to be brought under other laws, including Title VII, Title IX, Section 504, the ADA and the Age Discrimination in Employment Act, as appropriate.

²⁶⁹ This approach is consistent with the basic principle underlying the rule and derived from longstanding civil rights interpretations: Where an entity that receives Federal financial assistance is principally engaged in providing or administering health services, health insurance coverage, or other health coverage, all of its operations are covered by Section 1557. See discussion *supra* of § 92.2.

employee health benefit program, but only with regard to employees in the health program or activity. Thus, we noted that when a State receives Federal financial assistance for its Medicaid program, the State will be governed by Section 1557 in the provision of employee health benefits for its Medicaid employees, but not for its transportation department employees, assuming no part of the State transportation department operates a health program or activity.

In summary, unless the primary purpose of the Federal financial assistance is to fund employee health benefits, we proposed that Section 1557 would not apply to an employer’s provision of employee health benefits where the provision of those benefits is the only health program or activity operated by the employer.

We explained that absent the limitations in § 92.208, employers that receive Federal financial assistance for any purpose could be held liable for discrimination in the employee health benefit programs they provide or administer, even where those employers are not otherwise engaged in a health program or activity and where the use of Federal funds for employee health benefits is merely incidental to the purpose of the assistance. We noted that claims of discrimination in such benefits, brought against employers that do not operate other health programs or activities, could be better addressed under other applicable laws. For example, Title VII of the Civil Rights Act of 1964,²⁷⁰ the ADA,²⁷¹ and the Age Discrimination in Employment Act²⁷² address claims that an employer has discriminated in the provision of benefits, including health benefits, to its employees.

We proposed to apply the same analysis of employer liability under Section 1557 whether the employee health benefit program is self-insured or fully-insured by the employer. We provided that where an employer that would otherwise be covered under this section creates a separate legal entity to administer its employee health benefit plan, the employer would continue to be liable for the nondiscriminatory provision of employee health benefits to its employees; the employer, as a recipient, may not, through contractual or other arrangements, discriminate on

²⁷⁰ 42 U.S.C. 2000e–2000e–17.

²⁷¹ 42 U.S.C. 12101 *et seq.*

²⁷² 29 U.S.C. 621–634.

a prohibited basis against its employees.²⁷³

The comments and our responses regarding § 92.208 are set forth below.

Comment: One commenter expressed the view that while most churches or church boards providing employee health benefits through a church plan would not be covered under § 92.208, some might be covered under § 92.208(c). The commenter expressed the concern that churches that sponsor plans on behalf of numerous employers would not know whether any of those employers operated a health program or activity and received Federal financial assistance and thus would be required to either comply with Section 1557 requirements, even though most or all of the participating employers do not receive Federal financial assistance, or exclude the employer that receives Federal financial assistance from the plan.

Response: The comment reflects a misunderstanding about the application of § 92.208. This section of the regulation applies to employers, not to plan sponsors. In a church plan with multiple participating employers, the plan sponsor will be an entity other than the employer.²⁷⁴ In this scenario, when an employer is covered under § 92.208(c) and the plan sponsor is a different entity that does not receive Federal financial assistance, it is the employer's obligation, not the plan sponsor's, to ensure that the benefits it provides to employees of its health program or activity do not violate Section 1557. We note that a plan sponsor will be separately covered under Section 1557 if it receives Federal

financial assistance and is considered a covered entity under this rule.

Comment: One commenter expressed the view that treating a group health plan as an entity principally engaged in health coverage—and thereby subjecting all of its operations to Section 1557—undermines the limitations on employer liability under § 92.208. The commenter expressed concern that any employer that offers a self-insured group health plan to its employees would be accountable under Section 1557 for any discrimination by that group health plan.

Response: The commenter has misunderstood the relationship between the obligations of an employer and the application of the rule to a separate group health plan providing the employer's employee health benefit program. The fact that a group health plan is principally engaged in providing health services, health insurance coverage, or other health coverage, and therefore must comply with Section 1557 in all of its operations does not necessarily mean that an employer offering an employee health benefit program will be liable for a Section 1557 violation by the group health plan.²⁷⁵ Employers will be liable under Section 1557 only under the circumstances set forth in 92.208.

Comment: Two commenters requested clarification of whether tax credits claimed by an employer that purchases health insurance coverage through the Small Business Health Options Program (SHOP) MarketplaceSM and the health insurance plan purchased through a SHOP are covered by the rule.

Response: The tax credit to a small employer participating in the SHOP MarketplaceSM is not considered Federal financial assistance from the Department under this rule because the tax credit is not administered by the Department.

Comment: Some comments suggested eliminating or drastically revising § 92.208 to make clear that all covered entities are covered in their provision of employee health benefits. One commenter suggested adding "employee health benefits plan" to the definition of "health program or activity." Another asserted that § 92.208 is unnecessary because all group health plans are health programs or activities. One commenter recommended that OCR include in the regulatory text the substance of footnote 93 from the

preamble of the proposed rule,²⁷⁶ which clarifies that, regardless of whether an employer is liable for a discriminatory employee health benefit plan, an issuer that is a covered entity will be liable for discrimination in the health insurance coverage it offers to employers.

Response: We decline to eliminate or revise § 92.208 in the manner proposed by these commenters. As we explained in the preamble to the proposed rule,²⁷⁷ absent the limitations in § 92.208, employers that receive Federal financial assistance for any purpose could be held liable for discrimination in the employee health benefits they provide or administer, even where those employers are not otherwise engaged in a health program or activity and where the use of Federal funds for employee health benefits is merely incidental to the purpose of the Federal assistance. We do not believe that Congress intended for Section 1557 to apply in such circumstances. We reiterate that issuers that receive Federal financial assistance and are principally engaged in providing or administering health services, health insurance coverage, or other health coverage are liable for the health insurance coverage offered to employers in connection with a group health plan.

Comment: Some commenters asked us to make clear that employer-provided benefits are covered by the rule even if the employer does not contribute to the cost of these benefits and the entire cost is borne by the employee or other beneficiary.

Response: The rule does not limit employer liability for discrimination in employee health benefit programs to those benefits for which the employer pays for part or all of the cost. Thus, if an employer would otherwise be liable for discrimination in an employee health benefit program, the fact that the employer did not pay for part of the cost of these benefits does not remove it from the reach of 92.208.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.208 with minor technical revisions to ensure consistency with other parts of the final rule by adding the words "or other health coverage."

Nondiscrimination on the Basis of Association (§ 92.209)

In § 92.209 of the proposed rule, we specifically addressed discrimination

²⁷³ By contrast, with regard to the liability of the legal entity that an employer creates to administer its employee health benefit plan, *i.e.*, a group health plan, we proposed to analyze questions related to the application of Section 1557 on a case-by-case basis consistent with longstanding principles of nondiscrimination law. We will ask, for example, whether the group health plan itself receives Federal financial assistance, such as through receipt of Medicare Part D payments. If it does not, we will evaluate the group health plan's relationship with the employer in assessing whether Section 1557 applies to the group health plan. 80 FR at 54191 n. 94. We noted that a group health plan may be a covered entity under this rule if the group health plan receives Federal financial assistance, as it operates a health program or activity by virtue of its provision or administration of the employee health benefit program. 80 FR at 54191 n. 93.

²⁷⁴ Under ERISA, when a group health plan is established or maintained by a single employer, the plan sponsor is the employer, but when a group health plan is established or maintained by two or more employers, the plan sponsor is the association, committee, joint board of trustees, or other similar group of representatives of the parties who establishes or maintains the plan. In the case of a plan established or maintained by an employee organization, the plan sponsor is the employee organization. 29 U.S.C. 1002(16)(B).

²⁷⁵ However, under employment discrimination laws like Title VII, the employer may be liable for the health plan's discrimination. *See, e.g., Los Angeles Dept. of Water and Power v. Manhart*, 435 U.S. 702 (1978).

²⁷⁶ 80 FR at 54191 n. 93.

²⁷⁷ *Id.*

faced by an individual or an entity on the basis of the race, color, national origin, age, disability, or sex of an individual with whom the individual or entity is known or is believed to have a relationship or association. We explained that the language of Section 1557 makes clear that individuals may not be subject to any form of discrimination “on the grounds prohibited by” Title VI and other civil rights laws; the statute does not restrict that prohibition to discrimination based on the individual’s own race, color, national origin, age, disability or sex. Further, we noted that a prohibition on associational discrimination is consistent with longstanding interpretations of existing anti-discrimination laws, whether the basis of discrimination is a characteristic of the harmed individual or an individual who is associated with the harmed individual.²⁷⁸ A prohibition on associational discrimination is also consistent with the approach taken in the ADA, which includes a specific prohibition of discrimination based on association with an individual with a disability.²⁷⁹

The comments and our responses regarding § 92.209 are set forth below.

Comment: A few commenters recommended that OCR add the words “or deter” to the prohibition on associational discrimination, so that § 92.209 would read as follows: “A covered entity shall not exclude or deter from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in its health programs or activities on the basis of the race, color, national origin, age,

disability, or sex of an individual with whom the individual or entity is known or believed to have a relationship or association.”

Response: We believe the regulatory text, as it is currently written, encompasses this approach. It is well established in civil rights law that deterrence is a form of exclusion.²⁸⁰

Comment: Several comments recommended that the rule state that unlawful discrimination based on association occurs when a provider is subject to adverse treatment because the provider is known or believed to furnish, refer or support services that are medically appropriate for, ordinarily available to, or otherwise associated with a patient population protected by Section 1557.

Response: To clarify, the rule prohibits covered entities from discriminating against any individual or entity on the basis of a relationship or association with a member of a protected class. The term “individual or entity” includes providers. Thus, for example, an issuer covered by the rule may not use the fact that a provider’s clientele is primarily composed of individuals with limited English proficiency to disqualify an otherwise eligible and qualified provider from participation in the issuer’s network; such a decision would discriminate against the provider on the basis of the provider’s association with a national origin group. We believe that the regulatory text encompasses this approach.

Comment: Commenters asked OCR to clarify whether § 92.209’s prohibition of discrimination on the basis of association prohibits discrimination against individuals in same sex relationships.

Response: We will interpret the language of § 92.209 consistent with our interpretation of the term “on the basis of sex,” as described in § 92.4 above.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.209 as proposed without modification.

Subpart D—Procedures

Enforcement Mechanisms (§ 92.301)

In proposed § 92.301, we restated the language of Section 1557 regarding enforcement, which provides that the enforcement mechanisms under Title VI, Title IX, the Age Act, or Section 504 apply for violations of Section 1557. We noted that these existing enforcement

mechanisms include requiring covered entities to keep records and submit compliance reports to OCR, conducting compliance reviews and complaint investigations, and providing technical assistance and guidance. We further noted that where noncompliance or threatened noncompliance cannot be corrected by informal means, the enforcement mechanisms provided for and available under the civil rights laws referenced in Section 1557 include suspension of, termination of, or refusal to grant or continue Federal financial assistance; referral to the Department of Justice with a recommendation to bring proceedings to enforce any rights of the United States; and any other means authorized by law.²⁸¹ In addition, we provided that based on the statutory language, a private right of action and damages for violations of Section 1557 are available to the same extent that such enforcement mechanisms are provided for and available under Title VI, Title IX, Section 504, or the Age Act with respect to recipients of Federal financial assistance. We further provided that a private right of action and damages are available for violations of Section 1557 by Title I entities. We invited comment on these positions.

The comments and our responses regarding § 92.301 are set forth below.

Comment: Many commenters requested that OCR clarify that all enforcement mechanisms available under the statutes listed in Section 1557 are available to each Section 1557 plaintiff, regardless of the plaintiff’s protected class. Thus, for example, an individual could bring a race claim under the Age Act procedure and an age claim under the Title VI procedure.

Under this approach, given that the Age Act authorizes a private right of action for disparate impact claims, a private right of action would exist for disparate impact claims of discrimination on the basis of race, color, or national origin.

The commenters primarily rely on reasoning in *Rumble v. Fairview Health Services*,²⁸² in which the U.S. District Court for the District of Minnesota discussed the standards to be applied to Section 1557 private right of action claims and stated: “It appears Congress intended to create a new, health-specific, anti-discrimination cause of action that is subject to a singular standard, regardless of plaintiff’s protected class status. Reading Section 1557 otherwise would lead to an illogical result, as different enforcement

²⁷⁸ See, e.g., *McGinest v. GTE Service Corp.*, 360 F.3d 1103, 1118 (9th Cir. 2004), cert. denied, 552 U.S. 1180 (2008) (holding that harassment of white employee who associated with African American employees was discrimination under Title VII); *Tetro v. Elliot Popham Pontiac, Oldsmobile, Buick & GMC Trucks Inc.*, 173 F.3d 988, 993–96 (6th Cir. 1999) (holding that white plaintiff with biracial child stated a claim under Title VII based on his own race because Title VII protects victims of discriminatory animus towards third persons with whom one associates); *Parr v. Woodmen of the World Life Ins.*, 791 F.2d 888, 892 (11th Cir. 1986) (“Where a plaintiff claims discrimination based upon an interracial marriage or association, he alleges by definition that he has been discriminated against because of his race.”)

²⁷⁹ 42 U.S.C. 12182(b)(1)(E)(Title III); 28 CFR 35.130(g) (Title II). See generally http://www.eeoc.gov/facts/association_ada.html. Cf. *Loeffler v. Staten Island Univ. Hosp.*, 582 F.3d 268, 277 (2d Cir. 2009) (permitting associational discrimination claim under Section 504); *Falls v. Prince George’s Hosp. Ctr.*, No. Civ. A 97–1545, 1999 WL 33485550 at * 11 (D. Md. Mar. 16, 1999) (holding that parent had an associational discrimination claim under Section 504 when hospital required hearing parent to act as interpreter for child who was deaf). Cf. Questions and Answers About the Americans with Disabilities Act’s Association Provision.

²⁸⁰ See discussion of § 92.101(a) *supra*.

²⁸¹ See 45 CFR 80.8(a).

²⁸² No. 14–CV–2037 2015 WL 1197415 (D. Minn. Mar. 16, 2015).

mechanisms and standards would apply to a Section 1557 plaintiff depending on whether plaintiff's claim is based on her race, sex, age, or disability. For example, it would not make sense for a Section 1557 plaintiff claiming race discrimination to be barred from bringing a claim using a disparate impact theory but then allow a Section 1557 plaintiff alleging disability discrimination to do so."²⁸³

Similarly, many commenters requested that the regulation clarify that a private right of action exists for disparate impact claims, arguing, like commenters discussed above, that all enforcement mechanisms should be available to all Section 1557 complainants. A few commenters requested that the availability of a private right of action be addressed in the final rule itself, rather than in the preamble.

Response: OCR interprets Section 1557 as authorizing a private right of action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation. At the same time, OCR is incorporating its existing procedures for its administrative processing of complaints; thus, we will use our current processes to address age discrimination on the one hand and race, color, national origin, sex, or disability on the other hand. This approach will enable us to be consistent in our processing of complaints under OCR's other authorities in instances where we have concurrent jurisdiction under Section 1557 and the other civil rights laws it references. This approach is not intended to limit the availability of judicial enforcement mechanisms. We note as well that both the proposed and the final rule specify that a private right of action is available under Section 1557.

Comment: A few commenters suggested that the text of the regulation specifically mention the availability of compensatory damages. Although OCR discussed the availability of compensatory damages in the preamble of the NPRM, commenters recommended that explicit authorization for compensatory damages in the regulation would strengthen the enforcement of Section 1557.

Response: OCR has added a provision to § 92.301 to make clear in the regulation that compensatory damages are available. Our interpretation of Section 1557 as authorizing compensatory damages is consistent with our interpretations of Title VI, Section 504, and Title IX.

Comment: Many commenters requested that OCR involve the Department of Justice (DOJ) in all Section 1557 investigations and compliance reviews where DOJ has concurrent jurisdiction, and that OCR refer cases to DOJ for litigation, where appropriate.

Response: Although OCR recognizes the importance of working with DOJ and other agencies, it would not be a productive use of resources to include DOJ in every case in which it has concurrent jurisdiction. OCR has been enforcing Section 1557 since it became effective in 2010 and continues to investigate and resolve Section 1557 cases over which it has jurisdiction. OCR involves DOJ in investigations where appropriate and will continue to do so. And, as § 92.209 makes clear, OCR has the authority to refer cases to DOJ for litigation where efforts at compliance have been unsuccessful.

Comment: Some commenters recommended that HHS agreements with State agencies and State contracts with Medicaid managed care organizations include nondiscrimination provisions that obligate the State agencies to ensure compliance with nondiscrimination requirements.

Response: OCR agrees that nondiscrimination provisions in contracts help covered entities to ensure that contractors do not discriminate against program beneficiaries. Although this rule does not require such provisions in contracts, OCR has worked with HHS entities to include such language in their contracts in the past, and OCR will continue to look for opportunities to promote compliance with civil rights laws through nondiscrimination provisions in contracting in the future.

Comment: Several commenters recommended that the regulatory text specifically provide that OCR will conduct compliance reviews and perform outreach. These commenters expressed concern that individual complaint resolution, as an enforcement mechanism, will be inadequate to achieve widespread compliance with the Section 1557 final rule.

Response: We recognize the need for OCR to employ the full range of enforcement tools in order to ensure compliance with the law, and we intend to continue in our robust enforcement of Section 1557. We do not believe that any changes to regulatory text are necessary, since the rule contemplates and authorizes the suite of enforcement mechanisms that OCR has long employed.

Comment: Some commenters recommended that HHS, and not States, should be the primary enforcement agency for benefit design issues. These commenters asserted that State enforcement would lead to inconsistent results.

Response: OCR is responsible for enforcement with respect to benefit design issues under Section 1557. States have an important role in ensuring compliance with nondiscrimination requirements respecting insurance, including benefit design, under CMS regulations and applicable State laws. It is beyond the scope of this rulemaking to change State obligations under those laws.

Comment: Some commenters recommended that OCR be required to publish the outcomes of all resolved Section 1557 complaints and statistics regarding Section 1557 complaints received by OCR.

Response: We decline to accept this recommendation, but OCR will continue to include information and corrective action plans and resolution agreements on the OCR Web site.

Comment: Some commenters recommended that OCR allow at least a one-year period with no administrative sanctions if a covered entity can demonstrate good faith compliance. These commenters suggested that this approach will promote compliance while covered entities, OCR, and consumers become familiar with the requirements of the regulation.

Response: We appreciate the commenters' recommendation, but we decline to accept it because, while good faith is relevant under certain CMS regulations with which covered entities may be familiar, courts have not treated good faith as a consideration in assessing whether a covered entity is in compliance with the civil rights laws referenced in Section 1557. We are retaining this principle in interpreting whether a covered entity is in compliance with Section 1557. That said, OCR has the authority and discretion to consider a range of factors when reviewing cases and determining appropriate remedies, including consideration of steps taken by covered entities to ensure compliance with the law, compliance with other Federal regulations regarding the issue, timeframes for implementation of corrective action and resources to facilitate compliance.

Comment: Some commenters suggested that the final rule mandate training for employees of entities required to comply with the requirements of Section 1557.

²⁸³ *Id.* at *11.

Response: Although OCR encourages covered entities to train employees on compliance with Section 1557 periodically, OCR does not believe it is necessary for the final rule to mandate training. However, to facilitate training that covered entities choose to provide, we are preparing and will make available a training curriculum for their use in advance of the effective date of the rule. We also expect to engage in outreach and technical assistance to promote understanding of and compliance with the final rule.

Comment: Several commenters stated that the final rule should require OCR to perform unannounced, onsite reviews of covered entities to ensure compliance with Section 1557.

Response: While OCR may consider performing unannounced, onsite reviews where appropriate, OCR does not believe it is necessary to include a requirement to do so in the final rule.

Comment: Some commenters recommended that the regulation permit class actions and third party complaints in court. Other commenters recommended that the regulation provide for the availability of attorneys' fees in successful private suits. These commenters pointed out that many individuals who are subject to discrimination will be unable to afford a retainer for an attorney. Some commenters recommended that suits be allowed only in the State where the MarketplaceSM is located, not any Federal district court in a district in which a complainant resides.

Response: Although these issues are outside the scope of this regulation, nothing in Section 1557 changes the laws that otherwise would govern eligibility for attorneys' fees, including the Civil Rights Attorney's Fees Award Act of 1976,²⁸⁴ laws that otherwise would govern venue,²⁸⁵ or laws that otherwise would govern initiation of class action lawsuits.²⁸⁶

Comment: Some commenters suggested that the regulation prohibit issuers from including clauses requiring mandatory binding arbitration of Section 1557 complaints. These commenters asserted that such arbitration is unfair to consumers.

Response: We decline to accept the commenters' suggestion because it is outside the scope of this regulation.

Summary of Regulatory Changes

For the reasons set forth above and in the proposed rule and considering the comments received, we have revised

§ 92.301 to re-designate existing text as § 92.301(a) and add a new subsection (b) stating that compensatory damages for violations of Section 1557 are available in administrative and judicial actions, as they are under authorities referenced in Section 1557.

Procedures for Health Programs and Activities Conducted by Recipients and State-Based Marketplaces (§ 92.302)

In § 92.302, we proposed the procedures that will apply to enforcement of Section 1557 in health programs and activities conducted by recipients and State-based Marketplaces. We noted that the administrative procedures provided for and available under Title VI are found in the regulation implementing Title VI.²⁸⁷ We explained that these administrative procedures are incorporated into the regulation implementing Title IX²⁸⁸ and Section 504 with respect to recipients.²⁸⁹ In paragraph (a), we proposed to incorporate these procedures into Section 1557 with respect to race, color, national origin, sex, and disability discrimination.

We also explained that the administrative procedures provided for and available under the Age Act are found in the regulation implementing the Age Act.²⁹⁰ In paragraph (b), we proposed to incorporate these procedures into Section 1557 with respect to age discrimination.

In paragraph (c), we provided that an individual may bring a civil action in a United States District Court in which a recipient or State-based MarketplaceSM is located or does business, as provided for and available under Section 1557.

The comments and our responses regarding § 92.302 are set forth below.

Comment: A few commenters asserted that any enforcement provisions that apply to Health Insurance Marketplaces should apply whether the MarketplaceSM is operated by the State or Federal government.

Response: OCR declines to incorporate the commenter's request that Marketplaces operated by the Federal government be subject to the same enforcement provisions as Marketplaces operated by State governments. Under the regulations implementing Section 504, federally assisted programs, including federally assisted programs operated by States, and federally conducted programs are subject to separate enforcement

procedures.²⁹¹ OCR believes that this approach has worked successfully in the past and has decided to retain separate procedures for federally conducted health programs and activities, including Health Insurance Marketplaces operated by HHS, and other health programs and activities, including Health Insurance Marketplaces operated by States.

Comment: Some commenters suggested that OCR use the enforcement scheme of Title VI for all discrimination under Section 1557. By contrast, some commenters recommended that the final rule should require mediation for all Section 1557 complaints. A few commenters requested that OCR require exhaustion of administrative remedies before individuals could pursue a private right of action.

Response: OCR declines to adopt these recommendations. OCR has decided to retain administrative procedures and application of the procedures consistent with OCR's existing procedures for complaints. Mediation and exhaustion of administrative remedies will still be required for age discrimination allegations in complaints, but not for allegations of other covered types of discrimination.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.302 with two modifications. As addressed previously in the discussion of the comments on § 92.5 (Assurances), the text that was previously found at § 92.302(c) has been moved to § 92.302(d), and § 92.302(c) now clarifies OCR's ability to initiate enforcement procedures where a recipient or State-based MarketplaceSM fails to provide OCR with requested information.

Procedures for Health Programs and Activities Administered by the Department (§ 92.303)

In the proposed rule, we noted that Section 1557 expressly states that the enforcement mechanisms provided for and available under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of violations of Section 1557. We also noted that the administrative procedures provided for and available under Section 504—the only one of these statutes that applies to federally conducted, as well as federally assisted, programs—for programs and activities administered by the

²⁸⁴ 42 U.S.C. 1988.

²⁸⁵ See, e.g., 28 U.S.C. 1391.

²⁸⁶ See, e.g., 28 U.S.C. 1332.

²⁸⁷ 45 CFR 80.6–.11; 45 CFR pt. 81.

²⁸⁸ 45 CFR 86.71.

²⁸⁹ 45 CFR 84.61.

²⁹⁰ 45 CFR 91.41–.50.

²⁹¹ Compare 45 CFR 84.61 with 45 CFR 85.61–.62.

Department are found in the regulation implementing Section 504.²⁹² We provided that these procedures shall apply with respect to complaints and compliance reviews of health programs or activities administered by the Department, including the Federally-facilitated Marketplaces, concerning discrimination on the basis of race, color, national origin, sex, age, or disability.

In the proposed rule, we proposed to add two provisions that are not found in Section 504 enforcement procedures for programs conducted by the Department. We proposed that the first provision, which reflects OCR's practice under Section 504 and mirrors similar requirements under the Title VI regulation with regard to access to information, is designed to ensure that OCR has the ability to obtain all of the relevant information needed to investigate a complaint or determine compliance in a particular health program or activity administered by the Department.

We further proposed language prohibiting the Department, including Federally-facilitated Marketplaces, from retaliating against any individual for the purpose of interfering with any right or privilege under Section 1557 or the proposed rule or because the individual has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under Section 1557 or this proposed rule. We explained that Section 504 of the Rehabilitation Act, to which the Department is already subject, provides that the procedures, rights, and remedies under Title VI are available to any individual aggrieved by an act or failure to act by any recipient of Federal financial assistance or Federal provider of such financial assistance under Section 504. Thus, we noted that the prohibition on retaliation under Title VI²⁹³ would apply to the Department under Section 504. We noted that the retaliation provision in the proposed rule is simply an extension of this existing prohibition. We further noted that this provision is also in accordance with a similar requirement for recipients under the Title VI regulations. The Department should hold itself to the same standards to which it holds recipients of Federal financial assistance.²⁹⁴

²⁹² 45 CFR 85.61–.62.

²⁹³ 45 CFR 80.7(e).

²⁹⁴ Further, as the U.S. Supreme Court observed in *Jackson v. Birmingham Bd. of Educ.*, 544 U.S. 167, 180 (2005), protecting individuals from discrimination under Title IX “would be difficult, if not impossible, to achieve if persons who complain about sex discrimination did not have

Summary of Regulatory Changes

We did not receive any significant comments regarding § 92.303. For the reasons set forth in the proposed rule, we are finalizing the provisions proposed in § 92.303 without modification.

Information Collection Requirements

The notice of proposed rulemaking called for new collections of information under the Paperwork Reduction Act of 1995.²⁹⁵ As defined in implementing regulations,²⁹⁶ “collection of information” comprises reporting, recordkeeping, monitoring, posting, labeling and other similar actions. In this section, we first identify and describe the entities that must collect the information, and then we provide an estimate of the total annual burden. The estimate covers the employees’ time for reviewing and posting the collections required.

The final rule calls for the same collections of information as the notice of proposed rulemaking, with one addition: The cost estimates for covered entities to develop and implement a language access plan, should the covered entities choose to do so, given that development and implementation of a language access plan is one of the factors that the Director will consider, if relevant, in assessing whether a covered entity has met its obligation to take reasonable steps to provide meaningful access to each individual with limited English proficiency.

Title: Nondiscrimination in Health Programs and Activities.

OMB Control Number: XXXX–XXXX.

Summary of the Collection of Information: The final rule estimates four categories of information collection: (1) Submission of an assurance of compliance form, per § 92.5; (2) posting of a nondiscrimination notice and posting of taglines, under § 92.8; (3) development and implementation of a language access plan, anticipated per § 92.201; and (4) designation of a compliance coordinator and adoption of grievance procedures for covered entities with 15 or more employees, per § 92.7. Each category is described in the following analysis.

Under the final rule, each entity applying for Federal financial assistance, each health insurance issuer seeking certification to participate in a

effective protection against retaliation.” (citing to the brief of the United States as Amicus Curiae). The same principle is true for discrimination under Section 1557.

²⁹⁵ 44 U.S.C. 3501–3520.

²⁹⁶ 5 CFR 1320.3(c).

MarketplaceSM, and each entity seeking approval to operate a Title I entity is required to submit an assurance that its health programs and activities will be operated in compliance with Section 1557.

In addition, each covered entity subject to the final rule is required to post a notice of individuals’ civil rights and covered entities’ obligations, including acknowledging that the covered entity provides auxiliary aids and services, free of charge, in a timely manner, to individuals with disabilities, when such aids and services are necessary to provide an individual with a disability an equal opportunity to benefit from the entity’s health programs or activities; and language assistance services, free of charge, in a timely manner, to individuals with limited English proficiency, when those services are necessary to provide an individual with limited English proficiency meaningful access to a covered entity’s health programs or activities. Furthermore, each covered entity is required to post taglines in the top 15 languages spoken by individuals with limited English proficiency by relevant State or States, informing individuals with limited English proficiency that language assistance services are available.

Although the final rule does not require covered entities to develop a language access plan, the development and implementation of a language access plan is one factor that the Director will consider when evaluating a covered entity’s compliance with this rule. We anticipate that some proportion of covered entities will develop and implement a language access plan following issuance of the rule.

Additionally, each covered entity that employs 15 or more persons is required to adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557. Each covered entity is also required to designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557, including the investigation of any grievance communicated to it alleging noncompliance with Section 1557.

Need for Information: The requirement that every entity applying for Federal financial assistance, seeking certification to participate in a Health Insurance MarketplaceSM, or seeking approval to operate a Title I entity, submit an assurance of compliance, is similar to the current regulatory

requirements under Title VI,²⁹⁷ Section 504,²⁹⁸ and the Age Act.²⁹⁹ These requirements protect individuals by assuring that covered entities will comply with all applicable nondiscrimination statutes and their implementing regulations.

The posting of a notice of individuals' rights and covered entities' obligations and the posting of taglines in the top 15 languages spoken by individuals with limited English proficiency by relevant State or States are necessary to ensure that individuals are aware of their protections under the law, and are grounded in OCR's experience that failures of communication based on the absence of auxiliary aids and services and language assistance services raise particularly significant compliance concerns under Section 1557, as well as Section 504 and Title VI.

The development and implementation of a language access plan helps ensure meaningful access to persons with limited English proficiency to a covered entity's health programs and activities. While Title VI has long required covered entities to take reasonable steps to provide persons with limited English proficiency meaningful access, the addition of a language access plan brings specificity and increased probability of implementation of the requirement. Although the final rule does not require development and implementation of a language access plan, covered entities may choose to develop and implement a language access plan because the Director will consider, if relevant, the language access plan as one factor when assessing a covered entity's compliance with this rule.

The requirements that every covered entity that employs 15 or more persons adopt grievance procedures and designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557 are similar to requirements included in the Title IX and Section 504 implementing regulations. Through its case investigation experience, OCR has observed that the presence of a coordinator and grievance procedures helps to bring concerns to prompt resolution within an entity, leading to lower compliance costs and more efficient outcomes.

Use of Information: OCR will use this information to ensure covered entities' adherence to the statutory requirements imposed under Section 1557 and this final rule. OCR will enforce the

requirements by verifying during investigations of covered entities that an entity has submitted an assurance of compliance and posted the notice and taglines and, for each covered entity that employs 15 or more persons, that an individual has been designated to coordinate its compliance efforts and that appropriate grievance procedures have been adopted, as required.

Description of the Respondents: The respondents are: the Department, each entity that operates a health program or activity, any part of which receives Federal financial assistance, and each entity established under Title I of the ACA that administers a health program or activity. These include such entities as hospitals, home health agencies, community mental health centers, skilled nursing facilities, and health insurance issuers.

Number of Respondents: The number of respondents is estimated to include the 275,002 covered entities affected by the final rule.

Burden of Response: Because the Department provides the assurance of compliance and the final rule provides a sample Notice, sample taglines in 64 languages, and sample grievance procedures, the burden on respondents is minimal. Additionally, because all recipients of Federal financial assistance with 15 or more employees are already expected under other laws to have in place grievance procedures and a designated individual to coordinate their compliance responsibilities, the burden to comply with this requirement will be minimal for most respondents.

The requirement to sign and submit an assurance of compliance exists under other civil rights regulations (Title VI, Section 504, Title IX, the Age Act), and since the Department provides a copy of the Assurance of Compliance form to covered entities, OCR believes this requirement adds no extra burden. OCR believes that the time, effort, and financial resources necessary to comply with this requirement are considered part of the usual and customary business practice and would be incurred by covered entities during their ordinary course of business.

OCR estimates that the burden for responding to the proposed notice requirement is an average of 17 minutes to download and post the notice and that the burden to download and post taglines in the top 15 languages by relevant State or States is also an average of 17 minutes, for a burden total of 34 minutes on average at each of the 405,534 affected establishments (associated with the affected covered entities) in the first year following publication of the final rule. (See

Regulatory Impact Analysis, II. Costs, B.2. for a more detailed explanation of the differences between "firm" and "establishment.") We estimate that administrative or clerical support personnel would perform these functions. Based on the wage rate for a Clerical Support Worker (\$15.52) we estimate the annual burden for these two requirements to be approximately \$7.1 million after adjusting for overhead and benefits by adjusting the wage rate upward by 100%.

OCR estimates that the burden for developing a language access plan is approximately three hours of medical and health service manager staff time in the first year, and an average of one hour of medical and health service manager staff time per year to update the plan in subsequent years. The value of an hour of time for people in this occupation category, after adjusting for overhead and benefits, is estimated to be \$89.24 based on Bureau of Labor Statistics (BLS) data. As discussed later in this analysis, we estimate that approximately 135,000 entities will develop and implement language access plans, as part of the requirement to take reasonable steps to provide meaningful communication with persons with limited English proficiency. These assumptions imply that the total cost of the development of language access plans will be approximately \$36.0 million (269,141 entities \times 50% of entities \times 3 hours per entity \times \$89.24 per hour) in the first year and approximately \$12.0 million (269,141 entities \times 50% of entities \times 1 hour per entity \times \$89.24 per hour) per year in subsequent years.

Regarding the requirement that every covered entity that employs 15 or more persons adopt grievance procedures and designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557, based on OCR's complaint workload increase since the enactment of Section 1557, we anticipate that within the first five years following the rule's enactment, complaints will increase approximately 0.5% in the first year, 0.75% in the second year, and 1% in years three through five, but eventually will drop off as covered entities modify their policies and practices in response to this final rule. We estimate that medical and health service managers will handle the grievances, and that a 1% increase in complaints will require 1% of an FTE at each covered entity. Using the annual wage rate for medical and health service managers (\$103,680), adjusting for fringe benefits and overhead, and multiplying by the 41,250 entities

²⁹⁷ 45 CFR 80.4(a).

²⁹⁸ 45 CFR 80.5.

²⁹⁹ 45 CFR 91.33.

affected by this requirement, we estimate the annual burden for this requirement to be approximately \$42.8 million in year one, \$64.2 million in year two, and \$85.5 million for each year in years three, four, and five following publication.

Thus, the total estimated annual burden cost for the proposed information collection requirements will be approximately \$86.0 million in the first year, \$76.2 million in the second year, and \$97.5 million per year in years three through five following publication of the final rule.

We asked for public comment on the proposed information collection to help us determine:

1. Whether the proposed collection of information is necessary for the proper performance of the functions of OCR, including whether the information will have practical utility;

2. The accuracy of the estimated burden associated with the proposed collection of information;

3. How the quality, utility, and clarity of the information to be collected may be enhanced; and

4. How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology.

We received no comments with specific data in response to numbers one, two, or three above. With regard to question four, we received comments asking that the proposed collection of information be minimized and stating that it is burdensome for covered entities to develop notices to put in several locations in all their facilities. OCR responded by proposing that OCR develop a model notice of important information and model taglines, to minimize the burden on covered entities. The new cost analysis is included above, in this Information Collection section, as well as in the Regulatory Impact Analysis.

Regulatory Impact Analysis

I. Introduction

A. Executive Orders 12866 and 13563

Executive Order 12866³⁰⁰ directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563³⁰¹

is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. OMB has determined that this final rule is a “significant regulatory action” under Executive Order 12866. Accordingly, OMB reviewed this final rule.

In general, we received few comments with regard to the Regulatory Impact Analysis (RIA), and thus the analysis in the final rule remains fairly similar to the proposed rule, although there are some changes. The comments will be addressed in each section below, as appropriate.

B. The Need for a Regulation

Section 1557 of the ACA prohibits an individual from being excluded from participation in, denied the benefits of, or otherwise subjected to discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities. It applies to any health program or activity, any part of which is receiving Federal financial assistance, and to any program or activity that is administered by an Executive Agency or any entity established under Title I of the ACA.³⁰² The Secretary of the Department is authorized to promulgate regulations to implement Section 1557 under the statute and 5 U.S.C. 301. The purpose of this regulatory action is to implement Section 1557 of the ACA.³⁰³

One of the central aims of the ACA is to expand access to health care and health coverage for all individuals. Equal access for all individuals without discrimination is essential to achieving this goal. Discrimination in the health care context can often lead to poor and inadequate health care or health insurance or other coverage for individuals and exacerbate existing health disparities in underserved communities. Individuals who have experienced discrimination in the health care context often postpone or do not seek needed health care; individuals who are subject to discrimination are denied opportunities to obtain health care services provided to others, with resulting adverse effects on their health status. Moreover, discrimination in health care can lead to poor and ineffective distribution of health care resources, as needed resources fail to reach many who need them. The result is a marketplace comprised of higher medical costs due to delayed treatment,

lost wages, lost productivity, and the misuse of people’s talent and energy.³⁰⁴

We received comments suggesting that we consider either writing a more informative than prescriptive regulation or delaying the regulation. The Department’s current experience, however, points to the importance of a regulation that is prescriptive in the sense that it provides concrete guidance. The Department continues to receive many complaints of discrimination and continues to provide technical assistance and outreach in order to promote compliance. In addition, the majority of the comments from the public in response to the proposed rule favored speedy issuance of a strong regulation.

To help address the issues of nondiscrimination in health programs and activities, this regulation seeks to clarify the application of the nondiscrimination provision in the ACA to any health program or activity receiving Federal financial assistance from or administered by HHS or any entity established under Title I. Such clarity will promote understanding of and compliance with Section 1557 by covered entities and the ability of individuals to assert and protect their rights under the law.

In addition, Executive Order 13563 directs Federal agencies to improve regulations and regulatory review by promoting the simplification and harmonization of regulations and to ensure that regulations are accessible, consistent, and easy to understand. Regulations implementing the civil rights laws referenced in Section 1557 contain certain inconsistencies across common areas and subject matters, reflecting, among other things, differences in time and experience when the regulations were issued. The regulation attempts to harmonize these variations where possible.

We received comments asking that the regulation be written in plain language. The approach we adopt in the final rule is to simplify and make uniform, consistent, and easy to understand the various nondiscrimination requirements

³⁰⁴ Kristen Suthers, American Public Health Association: Issue Brief: Evaluating the Economic Causes and Consequences of Racial and Health Disparities (2008), http://hospitals.unm.edu/dei/documents/eval_cause_conse_apha.pdf; Timothy Waldmann, Urban Institute, Estimating the Cost of Racial and Ethnic Health Disparities (2009), <http://www.urban.org/sites/default/files/alfresco/publication-pdfs/411962-Estimating-the-Cost-of-Racial-and-Ethnic-Health-Disparities.PDF>; LaVera M. Crawley, David K. Ahn, and Marilyn A. Winkleby, Perceived Medical Discrimination and Cancer Screening Behaviors of Racial and Ethnic Minority Adults, 17(8), Cancer Epidemiol Biomarkers Prev., 1937–1944 (2008), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2526181/>.

³⁰² Patient Protection and Affordable Care Act, Public Law 111–148, 1557, 124 Stat. 119, 260, (2010) (codified at 42 U.S.C. 18116).

³⁰³ 42 U.S.C. 18116(c).

³⁰⁰ Exec. Order No. 12866, 58 FR 51735 (1993).

³⁰¹ Exec. Order No. 13563, 76 FR 3821 (2011).

and rights available under Section 1557, as appropriate.

The analysis that follows is similar to the analysis set forth in the proposed rule, except as specified in each of the sections that follow.

C. Examples of Covered Entities and Health Programs or Activities Under the Final Regulation

This final rule applies to any entity that has a health program or activity, any part of which receives Federal financial assistance from the Department, any health program or activity administered by the Department, or any health program or activity administered by an entity created under Title I of the ACA. The following are examples of covered entities as well as health programs or activities under the final rule.

1. Examples of Covered Entities With a Health Program or Activity, Any Part of Which Receives Federal Financial Assistance From the Department

This Department, through agencies such as the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare and Medicaid Services (CMS), provides Federal financial assistance through various mechanisms to health programs and activities of local governments, State governments, and the private sector. An entity may receive Federal financial assistance from more than one component in the Department. For instance, federally qualified health centers receive Federal financial assistance from CMS by participating in the Medicare or Medicaid programs and also receive Federal financial assistance from HRSA through grant awards. Because more than one funding stream may provide Federal financial assistance to an entity, the examples we provide may not uniquely receive Federal financial assistance from only one HHS component.

(1) Entities receiving Federal financial assistance through their participation in Medicare (excluding Medicare Part B) or Medicaid (about 133,343 facilities).³⁰⁵ Examples of these entities include:

Hospitals (includes short-term, rehabilitation, psychiatric, and long-term)
Skilled nursing facilities/nursing facilities—facility-based

Skilled nursing facilities/nursing facilities—freestanding
Home health agencies
Physical therapy/speech pathology programs
End stage renal disease dialysis centers
Intermediate care facilities for individuals with intellectual disabilities
Rural health clinics
Physical therapy—independent practice
Comprehensive outpatient rehabilitation facilities
Ambulatory surgical centers
Hospices
Organ procurement organizations
Community mental health centers
Federally qualified health centers

(2) Laboratories that are hospital-based, office-based, or freestanding that receive Federal financial assistance through Medicaid payments for covered laboratory tests (about 445,657 laboratories with Clinical Laboratory Improvement Act certification).

(3) Community health centers receiving Federal financial assistance through grant awards from HRSA (1,300 community health centers).³⁰⁶

(4) Health-related schools in the United States and other health education entities receiving Federal financial assistance through grant awards to support 40 health professional training programs that include oral health, behavioral health, medicine, geriatric, and physician's assistant programs.³⁰⁷

(5) State Medicaid agencies receiving Federal financial assistance from CMS to operate CHIP (includes every State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(6) State public health agencies receiving Federal financial assistance from CDC, SAMHSA, and other HHS components (includes each State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(7) Qualified health plan issuers receiving Federal financial assistance through advance payments of premium tax credits and cost-sharing reductions (which include at least the 169 health insurance issuers in the Federally-facilitated Marketplaces receiving Federal financial assistance through advance payments of premium tax credits and cost sharing reductions and at least 11 issuers operating in the State-Based Marketplaces that we were able to identify).³⁰⁸

³⁰⁵ U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, <http://www.hrsa.gov/about/budget/budgetjustification2016.pdf>.

³⁰⁷ *Id.* at 69.

³⁰⁸ Qualified Health Plans Landscape Individual Market Medical, Data.HealthCare.gov (2015),

(8) Physicians receiving Federal financial assistance through Medicaid payments, “meaningful use” payments, and other sources, but not Medicare Part B payments, as the Department does not consider Medicare Part B payments to physicians to be Federal financial assistance. The Medicare Access and CHIP Reauthorization Act amended Section 1848 of the Act to sunset “meaningful use” payment adjustments for Medicare physicians after the 2018 payment adjustment.

In the proposed rule, we estimated that the regulation would likely cover almost all licensed physicians because they accept Federal financial assistance from sources other than Medicare Part B. We noted that most physicians participate in more than one Federal, State, or local health program that receives Federal financial assistance, and many practice in several different settings, *e.g.*, they may practice in a hospital but also practice privately and develop nursing home plans of care at the local nursing home. We noted that although we have data, by program, for the number of physicians receiving payment from each program, there is no single, unduplicated count of physicians across multiple programs.³⁰⁹

In the proposed rule, we provided our best estimate of the number of physicians receiving Federal financial assistance by analyzing and comparing different data sources and drawing conclusions from this analysis. We noted that, based on 2010 Medicaid Statistical Information System data, about 614,000 physicians accept Medicaid payments and are covered under Section 1557 as a result.³¹⁰ This figure represents about 72% of licensed physicians in the United States when compared to the 850,000 in 2010.³¹¹ In addition, we noted that physicians receiving Federal payments from non-Part B Medicare sources would also come under Section 1557.³¹²

Earlier, before issuing the proposed rule, we identified several grant programs from various Department

<https://data.healthcare.gov/dataset/2015-QHP-Landscape-Individual-Market-Medical/mp8z-jtg7> (last visited May 3, 2016).

³⁰⁹ 80 FR at 54195.

³¹⁰ John Holahan and Irene Headen, Kaiser Commission on Medicaid and the Uninsured, Medicaid Coverage and Spending in Health Reform: National and State-by-State Results for Adults at or Below 133% FPL (2010), <http://kff.org/health-reform/report/report-and-briefing-on-medicaid-coverage-and/>. Estimates are based on data from FY 2010 Medicaid Statistical Information System.

³¹¹ Aaron Young, Humayun J. Chaudhry, Jon V. Thomas, & Michael Dugan, *A Census of Actively Licensed Physicians in the United States, 2012*, 99 no.2 J. Med. Reg. 11 (2013), <https://www.fsmb.org/Media/Default/PDF/Census/census.pdf>.

³¹² 80 FR at 54195.

agencies that fund a variety of health programs in which physicians participate and thus come under Section 1557, such as the National Health Service Corps, HRSA-funded community health centers, programs receiving National Institutes of Health (NIH) research grants, and SAMHSA-funded programs. In the proposed rule, we noted that physicians participating in a CMS gain-sharing demonstration project who receive gain-sharing payments would be covered under Section 1557 even if they did not participate in Medicare and Medicaid or any other health program or activity that receives Federal financial assistance. We also noted that there will be duplication and overlap with physicians who accept Medicaid or Medicare meaningful use payments, or other payments apart from Medicare Part B payments. Nevertheless, we noted that at least some of these physicians add to the total number of physicians reached under Section 1557 because some of them are not duplicates and do not accept Medicaid or Medicare meaningful use payments. We noted that although we do not have an exact number, adding these physicians may bring the total participating in Federal programs other than Medicare Part B to over 900,000.

In the proposed rule, when we compared the upper bound estimated number of physicians participating in Federal programs other than Medicare Part B (over 900,000) to the number of licensed physicians counted in HRSA's Area Health Resource File (approximately 890,000), we concluded that almost all practicing physicians in the United States are reached by Section 1557 because they accept some form of Federal remuneration or reimbursement apart from Medicare Part B.³¹³

We invited the public to submit information regarding physician participation in health programs and activities that receive Federal financial assistance. We received no comments that would change the estimates that we provided; thus, the analysis in this final rule includes the same numbers of physicians as in the proposed rule.

2. Examples of Health Programs or Activities Conducted by the Department

This final rule applies to the Department's health programs and activities, such as those administered by CMS, HRSA, CDC, Indian Health Service (IHS), and SAMHSA. Examples include the IHS tribal hospitals and

clinics operated by the Department and the National Health Service Corps.

3. Examples of Entities Established Under Title I of the ACA

This final rule applies to entities established under Title I of the ACA. According to the CMS Center for Consumer Information and Insurance Oversight (CCIIO), there are Health Insurance Marketplaces covering 51 jurisdictions: (17 State-based-Marketplaces and 34 Federally-facilitated Marketplaces). The final rule covers these Health Insurance Marketplaces.

II. Costs

It is important to recognize that this final rule, except in the area of sex discrimination, applies pre-existing requirements in Federal civil rights laws to various entities, the great majority of which have been covered by these requirements for years. Because Section 1557 restates existing requirements, we do not anticipate that covered entities will undertake new actions or bear any additional costs in response to the issuance of the regulation with respect to the prohibition of race, color, national origin, age, or disability discrimination, except with respect to the voluntary development of a language access plan. However, we also note that the prohibition of sex discrimination is new for many covered entities, and we anticipate that the enactment of the regulation will result in changes in action and behavior by covered entities to comply with this new prohibition. We note that some of these actions will impose costs and others will not.

Section 1557 applies to the Health Insurance Marketplaces. We note that these entities, along with the qualified health plan issuers participating in the Health Insurance Marketplaces, are already covered by regulations issued by CMS that prohibit discrimination on the basis of race, color, national origin, sex, gender identity, sexual orientation, age, or disability. Thus, we note that the impact of Section 1557 on these entities is limited.

We received a few comments that indicated that the costs of compliance may be more than anticipated in the proposed rule. We have revised the analysis in this final rule based upon the comments and upon an updated statistical review of the health programs and activities.

The following regulatory analysis examines the costs and benefits that are attributable to this regulation only.

We first analyze the costs we expect the final rule to create for covered entities. We anticipate that the final rule

will place costs on the covered entities in the areas of: (1) Training and familiarization, (2) enforcement, (3) posting of the nondiscrimination notice and taglines, and (4) revisions in policies and procedures, and may place costs on covered entities in the voluntary area of development of a language access plan. Then we examine the potential benefits the rule is likely to produce. In the subsequent analyses of costs in this RIA and the Regulatory Flexibility Act (RFA), we use data sets from the Census Bureau³¹⁴ and BLS³¹⁵ for estimating burdens.

A. Assumptions

In the proposed rule, we made the following cost assessment based on certain key assumptions, which include: (1) We assume that promulgation of this regulation will trigger voluntary activity on the part of covered entities that would not have occurred absent the promulgation of the regulation—which generates both costs and corresponding benefits; (2) to the extent that certain actions are required under the final rule where the same actions are already required by prior existing civil rights regulations, we assume that the actions are already taking place and thus that they are not a burden imposed by the rule; (3) although the regulation does not require training at any specific time, we assume that covered entities may voluntarily provide one-time training to some employees on the requirements of the regulation at the time that the regulation is published; and (4) we assume that employers are most likely to train employees who interact with the public and will therefore likely train between 40% and 60% of their employees, as the percentage of employees that interact with patients and the public varies by covered entity. For purposes of the analysis, we assume that 50% of the covered entity's staff will receive one-time training on the requirements of the regulation. We use the 50% estimate as a proxy, given the lack of certain information as described below. For the purposes of the analysis, we do not distinguish between employees whom covered entities will train and those who obtain training independently of a covered entity.

B. Training and Familiarization

In the proposed rule, we counted the cost of training on all aspects of the

³¹⁴ U.S. Census Bureau, Statistics of U.S. Businesses, <http://www.census.gov/econ/sub/> (last visited May 3, 2016).

³¹⁵ U.S. Dep't of Labor, Bureau of Labor Statistics, May 2015 National Occupational Employment and Wage Estimates, http://www.bls.gov/oes/2014/may/oes_nat.htm (last visited May 3, 2016).

³¹³ The Area Health Resource File itself double counts physicians who are licensed in more than one state. See *infra* discussion below at II.C.1.a.

regulation, not only on the new responsibilities under the regulation, as we believe covered entities will want to offer comprehensive training to employees, recognizing that refresher training can provide value. We invited comment on whether we should count only the cost of training on new responsibilities under the regulation. The comments we received supported our assumption regarding training on all aspects of the regulation, and therefore the final rule keeps this assumption.

In the proposed rule, we also assumed that covered entities will provide some workers (not all workers) a one-time awareness or familiarization training regarding the requirements in the regulation at the time of its issuance. We noted that many employees may work “behind the scenes” at large entities, and may not have contact with patients or the general public or otherwise have duties impacted by the final rule’s requirements and therefore may have little need for training. However, we noted that we are uncertain which employees those are. Furthermore, we noted that we do not know whether an entity rotates employees into different positions that may have patient contact or relevant duties, or whether, over time, an employee will switch to a position that places him or her in such a position, which may create a need for training. Although we received one comment suggesting that we include all employees in the training, the comment did not provide evidence or data to support including all employees. Otherwise, we received no comments to the contrary; therefore, the final rule makes the same assumption that the proposed rule did, that covered entities will provide some (not all) workers a one-time familiarization training.

In the proposed rule, we also noted that we lack information on State and local regulations that may require employees to receive training on civil rights provisions and whether those provisions are more or less rigorous than the ones we propose. Thus, workers in covered entities in State and local jurisdictions with civil rights provisions more robust than the ones we propose may need only minimal training. In State and local jurisdictions where civil rights provisions are not more robust, workers may need more training. As stated above, because we lack data on covered entities’ training practices, we are assuming that covered entities will voluntarily provide training on the final rule for between 40% and 60% of their staffs. Further analysis of state requirements revealed that the states do vary in the robustness of their civil rights requirements, as we assumed

in the proposed rule. Therefore, we chose 50% of the employees, the average between 40% and 60%.

Based on comments we received, we added a category of training, for a one-time familiarization by a manager, after the final rule has been published. The manager will need to study and understand the regulation well enough to make assessments of how the entity will promote compliance with the rule, including assessing the training needs of the staff and the costs associated with the training.

In the following section, we identify the pool of workers and staff that we anticipate may need education about the final rule. Next, we identify the covered entities that may choose to train their staffs to provide this knowledge. Last, we estimate the costs of the training materials and the worker time that will be spent in training.

1. Number of Individuals Who Will Receive Training

a. Health Care Staffs and Managers

The first category of health care staff that may receive training is comprised of health diagnosing and treating practitioners. This category includes physicians, dentists, optometrists, physician assistants, occupational, physical, speech and other therapists, audiologists, pharmacists, registered nurses, and nurse practitioners. The BLS occupational code for this grouping is 29–1000 and the 2014 reported count for this occupational group is approximately 4.8 million.

The second category of health care staff that we assume will receive training is comprised of degreed technical staff (Occupation code 29–2000) and accounts for 2.9 million workers. Technicians work in almost every area of health care: From x-ray to physical, speech, psychiatric, dietetic, laboratory, nursing, and records technicians, to name but a few areas.

The third category of health care staff that we assume will receive training is comprised of non-degreed medical assistants (Occupation code 31–0000), and includes psychiatric and home health aides, orderlies, dental assistants, and phlebotomists. Health care support staffs (technical assistants) operate in the same medical disciplines as technicians, but often lack professional degrees or certificates. We refer to this workforce as non-degreed compared to medical technicians who generally have degrees or certificates. There are approximately 3.9 million individuals employed in these occupations.

The fourth category of health care staff that we assume will receive

training is health care managers (approximately 0.3 million based on BLS data for occupation code 11–9111). Because we assess costs of familiarization with the regulation for one manager at each entity, we assume that those managers will have already become familiar with the regulation and will not need additional training.

The fifth category of health care staff that we assume will receive training is office and administrative assistants—Office and Administrative Support Occupation (Occupation code 43–0000). These workers are often the first staff patients encounter in a health facility and, because of this, covered entities might find it important that staff, such as receptionists and assistants, receive training on the regulatory requirements. Approximately 2.7 million individuals were employed in these occupations in health facilities in 2014.³¹⁶

One comment asked that outreach workers be explicitly included as a category to be trained. We assume that outreach workers are included in the five categories listed above, especially in the manager category.

Below is a summary table of individuals employed in the health care sector.

TABLE 1—HEALTH CARE EMPLOYEES WHO MAY NEED TRAINING

Health diagnosing and treating practitioners	4,833,840
Degreed technicians	2,876,000
Non-degreed technicians	3,940,500
Medical and health services managers	310,320
Office and administrative support staff	2,747,330
Total	14,707,990

b. Employees Working for the Federally-Facilitated Marketplaces and State-Based Marketplaces and Issuers in Those Marketplaces

We have data from CMS/CCIIO on the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces.³¹⁷ We assume that many issuers that operate in the Federally-facilitated Marketplaces also operate in the State-based Marketplaces. However, to the extent there are issuers who operate in a State-based MarketplaceSM

³¹⁶ U.S. Dep’t of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2014 National Occupational Employment and Wage Estimates, United States, http://www.bls.gov/oes/2014/may/oes_nat.htm (last visited May 3, 2016). This code includes health care sector data for health care and social assistance (including private, State and local government hospitals).

³¹⁷ Qualified Health Plans Landscape Individual Market Medical (2015), *supra* note 308.

only, an estimate of their employees will not be included in our count of issuers (derived from the CCIIO tables of issuers participating only in the 34 jurisdictions with Federally-facilitated Marketplaces). We are basing our calculations on the number of employees working for those issuers participating in the Federally-facilitated Marketplaces and we assume, as noted above, that some of the same issuers and employees serve the State-based Marketplaces. Determining the number of employees working for issuers participating in the Health Insurance Marketplaces is challenging because we have no data directly linking the number of employees to our data on participating issuers in the Federally-facilitated Marketplaces. Consequently, we must impute the number of employees working for issuers participating in the Federally-facilitated Marketplaces and, by extension, employees working for issuers in State-based Marketplaces.

We performed this imputation by first identifying the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces. To determine the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces, we looked at the 2015 Qualified Health Plan Landscape Individual and Small Business Health Options Program Market Medical files.³¹⁸ The Qualified Health Plan Landscape Individual Market Medical file contains over 100,000 line items, and the Small Business Health Options Program Market Medical file contains over 50,000 line items listing each Federally-facilitated MarketplaceSM plan for each county by metal level (bronze, silver, gold, and platinum) and catastrophic plans provided by each issuer. To determine the number of issuers in the individual and Small Business Health Options Program Marketplaces, we removed all plan line items to reduce the count to an unduplicated count of the issuers in the Federally-facilitated Marketplaces. We identified 155 individual plan issuers and 14 issuers in the Small Business Health Options Program that only issued group plans to employees of employers participating in the Small Business Health Options Program. Our total count of 169 issuers differs from the CCIIO sources, which counted issuers in each State in which they operated. For example, a national issuer such as Aetna that offers coverage through Federally-facilitated Marketplaces operating in several States was counted separately by CCIIO for

each State in which it was qualified, whereas we counted it only once.³¹⁹

In addition to 169 issuers participating in Federally-facilitated Marketplaces, we are aware of 11 issuers participating only in the State-based Marketplaces. Thus, we calculated that the total number of issuers included in the analysis of covered issuers equals 180.

We next analyzed the number of employees working in the health insurance industry in the following way. Using Census Bureau 2011 payroll and employment data (the latest data available) for North American Industry Classification System 524114—Direct Health Insurance,³²⁰ we attempted to match the number of employees to the health insurance entities. The Census data permitted us to divide all health insurance issuers into “large” (500 or more employees) and “small” (fewer than 500 employees) issuers, and from that we were able to estimate the number of employees for large and small issuers.

The Census data shows 805 small issuers and 180 large issuers. The ratio of small to large issuers is about 4.5 small issuers for every large issuer. We assume the ratio of small to large issuers in the Health Insurance Marketplaces is approximately the same as the ratio in the Census table. We asked for public comment on this assumption, and we received no comments to the contrary.

Applying this ratio to the issuers in the Federally-facilitated Marketplaces, we get 131 small issuers and 38 large issuers. We assume that the 11 issuers (for which we have data and have thus identified) operating in the State-based Marketplaces are likely to be classified as small, based on Census workforce data. Therefore, we are adding them to the 131 small issuers identified above, bringing the total number of small issuers to 142.

Based on the Census data, the average number of employees in a small issuer is 34 and the average number of employees in a large issuer is 2,300. If we multiply the number of issuers by the number of employees, there are 4,828 employees of the 142 small issuers and 87,400 employees of the 38 large issuers. The combined total number of employees for small and large issuers in the Marketplaces is estimated to be 92,228 employees.

³¹⁹ We count the issuer only once because we assume the same enterprise will minimize training costs by preparing the same training materials for all its employees nationally.

³²⁰ U.S. Census Bureau, Statistics of U.S. Businesses (SUSB) (2011), <http://www.census.gov/econ/susb/>.

With respect to the majority of issuers operating in a State-based MarketplaceSM that we have not been able to identify but would also be subject to the regulation, we do not have any direct data. However, the workforce data we have from the Census tables covers employees regardless of their work site. If any of the 169 issuers identified above operating in the Federally-facilitated Marketplaces also operate in the State-based Marketplaces, then some portion of the nearly 92,000 employees imputed to be working for the issuers in the Federally-facilitated Marketplaces may also be working for issuers operating in the State-based Marketplaces. Thus, in effect, we are including employees working for issuers that operate in both the State-based Marketplaces and the Federally-facilitated Marketplaces in our count of employees who likely will receive training on the regulation.

At the same time that we include employees who work for issuers operating in both the Federally-facilitated Marketplaces and State-based Marketplaces, we lack direct data on issuers participating only in State-based Marketplaces. We are not able to include employees that work for insurance issuers that operate only in State-based Marketplaces, such as New York or California, which would be subject to the proposed rule. We invited public comment on ways we could identify issuers that participate only in State-based Marketplaces and the number of employees they employ. We did not receive any comments that identified ways we can better identify these issuers.

A third category of workers who may need to be trained are navigators receiving Federal financial assistance to support the functions they perform in Federally-facilitated Marketplaces, such as assisting applicants to enroll in qualified health plans through the MarketplaceSM. CMS has awarded grant funding to 100 Navigator entities.³²¹ In the proposed rule, we estimated that 2,797 navigators worked for 92 Navigator entities, which implies 30.4 employees per entity. We lacked data on the number of employees of these Navigator entities, and we thus applied the previous estimate of 30.4 employees per Navigator entity to estimate in the

³²¹ CMS awards \$67 million in Affordable Care Act funding to help consumers sign-up for affordable Health Insurance MarketplaceSM coverage in 2016, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-09-02.html> (last visited May 3, 2016).

³¹⁸ *Id.*

final rule that 3,040 employees work for these entities.

We invited public comment on our approach to estimating the number of employees per issuer based on the Census data and sought any public information on issuers who operate only in State-based Marketplaces. We did not receive comments that changed our assumptions regarding types and numbers of employees working for Marketplaces. Thus, the final rule applies the estimate of the number of navigators per Navigator entity to the most recent number of Navigator grantees.

c. Medicaid and State and Local Health Department Employees

The Census Bureau State government payroll and employment data for 2012 shows the number of full-time employees working in State hospitals and departments of health as 531,251.³²² The State Medicaid Operations Survey: Fourth Annual Survey of Medicaid Directors reports that State Medicaid agencies employed between 27 and 3,853 full-time employees with a median workforce level of 455 employees.³²³ Multiplying the median level of workers by 56 Medicaid agencies adds 25,480 workers to the number of State health and hospital workers in health departments, bringing the total to 556,731 employees. (Although a more appropriate method of calculating the total would be to use the mean as the multiplier, OCR used the median because the mean was unavailable.) However, this number double counts medical personnel that were previously counted as discussed in part I.C.1.a (regarding health care staffs and managers who will receive training) in this RIA.

To address this problem, we looked at the BLS industry data for North American Industry Classification System code 999201: State government, including schools and hospitals, we identified 442,680 personnel employed by State governments.³²⁴ Subtracting this number from the 556,731 employees we identified employed in State government health services and

Medicaid programs, results in 114,051 additional State employees who may obtain training on the provisions of the regulation.

d. Non-Health Care Personnel in Pharmacies

The 2012 Census data for all U.S. industries identifies 43,343 pharmacy establishments. The number of employees presented in the Census data includes both pharmacists and non-pharmacist personnel. At this point, we must refer back to the BLS data on the number of health care workers reported for 2014 because the BLS data divides the pharmacy workforce by occupation. The number of employees that BLS reports were employed in pharmacies for 2014 is 708,660. The number of health care workers discussed in subsection II.C.1.a. above includes 348,190 individuals counted above in occupation codes 11–9111, 29–0000 and 31–0000 reported to be working in pharmacies.³²⁵ Because we already counted the costs of health care workers employed in pharmacies in the analysis of health care staff, to achieve a more accurate estimate of the number of non-health care pharmacy workers, we must subtract the 348,190 health care staff from the total workforce BLS reports. Removing health care staff from the BLS data yields a net of 360,470 non-health care pharmacy workers in pharmacies who may receive training on the final rule.

The following table shows the total number of employees whom we estimate will receive training; that is, the table shows the 50% of total workers whom we estimate may receive training. The table does not include HHS employees conducting HHS health programs or activities because there are roughly 65,000 HHS total employees and many of these employees do not work in health programs or activities administered by HHS. For those employees who do work in health programs or activities administered by HHS, many may not have direct beneficiary contact. Given these limitations, we estimate the number of employees added would be small and have little impact on overall cost.

TABLE 2—WORKERS WHO MAY RECEIVE TRAINING ON THE REGULATION

Medical health staffs and managers	7,216,494
Employees working for 180 issuers in the Health Insurance Marketplaces	46,114
State health employees	55,442
Navigators	1,520
Pharmacy workers (excluding health care personnel)	180,235
Total	7,637,306

2. Number of Covered Entities That May Train Workers

Just as there are a number of data sources for counting workforce, there are various sources for counting the number of health care entities. Many covered entities are controlled or owned by a single corporate entity, and one can count each individual entity separately or count only the single corporate enterprise. For example, a multi-campus facility or vertically integrated entity that owns a hospital, a nursing home, and a home health agency and also operates an accountable care organization could count each of these entities separately—as does Medicare—or count them only once, with each entity treated as part of the corporate entity. At this point, we make two assumptions: (1) Albeit not required to do so by the regulation, each covered entity will provide some training to its staff on the requirements of the regulation; and (2) when entities are controlled or owned by a corporate entity, the corporate entity will supplement or make any desired modification to the OCR training materials and distribute the training materials. We believe this last point to be especially true because rather than have each entity prepare its own training materials, the corporate entity is more likely to prepare one set of training materials and distribute the materials to its individual entities. This is because the corporate entity saves money by preparing a limited set of training materials and assures uniform quality and consistency in its policies across all its entities. It is also possible that some local health centers in a State may be managed from a central location that handles logistics and training materials. Therefore, we propose using the 2012 Census table that presents the number of entities, referred to as firms in the Census tables, to count the number of health care entities. In the Census data, a corporate entity is referred to as a “firm” and the corporation’s facilities are “establishments.” When a firm has one

³²² U.S. Census Bureau, Government Employment & Payroll (2013), <http://www.census.gov/govs/apes/>.

³²³ Nat’l Ass’n of State Medicaid Dirs, State Medicaid Operations Survey: Fourth Annual Survey of Medicaid Directors, at 5 (Nov. 2015) http://medicaiddirectors.org/wp-content/uploads/2015/11/namd_4th_annual_operations_survey_report_-_november_2_2015.pdf.

³²⁴ U.S. Dep’t of Labor, Bureau of Labor Statistics, May 2015 National Occupational Employment and Wage Estimates by ownership, http://www.bls.gov/oes/2014/may/oes_nat.htm (last visited May 3, 2016).

³²⁵ U.S. Dep’t of Health & Human Servs., Health Res. & Servs. Admin., Area Health Resource Files, <http://ahrh.hrsa.gov/> (last visited May 3, 2016). The Area Health Resource File reports 272,022 pharmacists licensed in 2014.

establishment, the establishment is the firm.

Another difficulty we face in using these data sources is that the Census data captures all entity types that fit the definition of a health care service entity, including entities such as private retirement communities that are unlikely to receive Federal financial assistance and thus would not be covered by Section 1557. In our use of the Census data, we attempted to exclude types of entities that are not likely to receive Federal financial assistance by excluding retirement communities and other similar type entities in the file, but we have included entities that may receive Federal financial assistance, such as community health centers and residential centers for individuals with intellectual disabilities.

To test our success in producing a list of covered entities from the Census data, we compared the number of entities we

selected from the Census data and the number of entities included in the CMS Provider of Service file. However, to make the lists comparable, we had to remove the count of Clinical Laboratory Improvement Act laboratories from the CMS Provider of Service data files. There are close to 450,000 Clinical Laboratory Improvement Act laboratories located in hospitals, clinics, outpatient centers, and doctors' offices. Only a few thousand of these laboratories serve the public. The majority of laboratories serve the facility in which they are housed—including them in our comparison would grossly distort this comparison.

If we add the entities in the Provider of Service file (excluding Clinical Laboratory Improvement Act laboratories) and the number of community health centers to our list of affected entities that are not included in the Provider of Service file, we get a total of 134,543 entities. Using the

Census data, minus the categories for medical laboratories, we obtain a total of 139,164 covered entities. It is evident that these numbers are very similar. However, as discussed earlier, we propose using only the number of firms for the analysis of the number of entities possibly conducting training, that is, 70,384 firms. As noted, we believe firms and not establishments will modify or supplement materials and train employees.

In addition to the firms we include from the Census file, we must add physicians' office firms and pharmacy firms because they may also need to train some workers. Physicians' office firms and pharmacy firms are generally referred to as physician group practices and pharmacy chains.

Below we present the types and number of firms that we estimate will take part in the training for the regulation.

TABLE 3—NUMBER OF HEALTH CARE ENTITY FIRMS EXPECTED TO TAKE PART IN TRAINING

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
621491	HMO medical centers	104
621492	Kidney dialysis centers	492
621493	Freestanding ambulatory surgical and emergency centers	4,121
621498	All other outpatient care centers	5,399
6215	Medical and diagnostic laboratories	7,958
6216	Home health care services	21,668
6219	All other ambulatory health care services	6,956
62321	Residential intellectual and developmental disability facilities	6,225
6221	General medical and surgical hospitals	2,904
6222	Psychiatric and substance abuse hospitals	411
6223	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing care facilities (skilled nursing facilities)	8,623
44611	Pharmacies and drug stores	18,852
6211	Offices of physicians	185,649
524114	Insurance Issuers	180
	Navigator grantees	100
Total Entities		275,002

3. Training and Familiarization Costs

a. Cost of Training Materials and Presentations

There are two components to the cost of training the workers we identified in the previous section: (1) The cost of training materials that is based on the number of covered entities identified in the previous section; and (2) the cost of employee time spent in training.

OCR estimates, based on its experience of training employees on other regulations it enforces, that training employees on this regulation will take about one hour of an employee's time. Based on discussions with firms that develop training materials, we estimate that developing

or presenting materials for a one-hour course would cost about \$500. However, before the effective date of the rule, OCR will provide covered entities with training materials that will cover the key provisions of the regulation that can be used by entities in conjunction with their own training materials. We estimate that OCR preparing the training materials on the regulation will substantially reduce the material preparation burden to covered entities and reduce the cost by about three quarters, or about \$375 per entity. Therefore, the costs to entities will equal \$125 multiplied by the number of entities that will prepare and present training materials. Based on its experience in preparing training

materials for other civil rights and HIPAA regulations, OCR expects to spend \$10,000 to develop training materials that will prepare health care workers and managers to effectively implement the Section 1557 regulation.

Training materials can be presented in a number of ways. A common method for offering training materials is through e-courses that are distributed over an entity's computer network. Another method is to offer lectures to selected employees/staff and then have attendees present the materials to their co-workers as part of train-the-trainer programs. For small entities, one lecture session may be given to all employees. Regardless of presentation mode, we estimate that the cost of training via an e-course will be

the same as the cost of training through a lecturer for a train-the-training approach: \$125 per entity.

Applying the \$125 per course materials to the number of firms ($\$125 \times 275,002$)—including the 169 health insurance issuers—equals \$34.4 million for the cost of developing training materials.

b. Cost of Employee Time

The next step is to compute the cost of employee time for training and familiarization. This involves taking the hourly wage rate times the amount of time that a new activity will require, times the number of employees expected to undertake the activity as a result of the rule. We use data from the BLS on median wage rates by occupation to estimate wages throughout this analysis. We are uncertain about how many employees identified in the workforce above will actually seek and obtain training and how many firms in the health sector will offer training. However, for the purposes of this analysis we assume that all firms may offer some training to their staffs, but because the training is voluntary, and because only a portion of employees who have direct patient contact or otherwise have duties impacted by the regulation may require or take training, we assume that 50% of employees will receive training. We assume that training will require an average of one hour of time for each participating employee.

The occupation code 29–1000 (health care practitioners) applies to the 4.8 million professional staff and degreed technical staffs we discussed above. The BLS reports the median hourly wage for this code as \$36.26. We estimate one hour of a worker's time would be required for training. To this amount we must add 100% for fringe benefits and overhead, which yields an adjusted hourly wage per employee of \$72.52. Assuming that half of the 4.8 million health care practitioners identified earlier receive or obtain training (2.4 million workers), and multiplying this number by the hourly employee wage plus fringe benefits and overhead for one hour equals slightly more than \$175.3 million in training costs for practitioners.

We note that one commenter suggested that we use a factor higher than 100% to adjust wages for overhead and benefits. However, the commenter's argument is based on Federal overhead rates for contracts, and not evidence of the resource costs associated with reallocating employee time. As a result, we do not adopt the commenter's recommendation, and we continue to

use the Department's standard of 100% for overhead and fringe benefits.

For the degreed health care work force in occupation 29–2000, the median hourly wage is \$19.92. Adding 100% for fringe benefits and overhead equals \$39.84. The total training cost for one hour of training for half of the 2.9 million degreed technical staff (1.44 million workers) is about \$57.3 million. In addition, we must add the cost of training non-degreed staff (reported in occupation 31–0000) who earn a median hourly wage of \$12.71. Adding 100% for fringe benefits and overhead to the \$12.71 median hourly wage rate yields an adjusted wage of \$25.42. Multiplying this amount by half of the 3.9 million workforce yields a cost of \$50.1 million.

To these amounts we must add the cost associated with familiarization and training for the medical and health service managerial staff, of which there are 300,320 individuals with a median hourly pay rate of \$44.62. Adding 100% for fringe benefits and overhead gives us an adjusted hourly wage of \$89.24. We assume that an average of one person in this occupation will spend an average of two hours becoming familiar with the final rule's requirements upon its publication at each of the 275,002 entities covered by the rule. These assumptions imply familiarization costs of \$49.1 million. We assume that half of the remaining managers receive training. This implies that 12,659 managerial staff will receive an hour of training, which results in a cost of \$1.1 million. This implies that total costs for training and familiarization for this occupation category comes to \$50.2 million.

The cost of training occupation code 43–0000, office and administrative support workers employed in covered health care entities, is the product of the median hourly rate of \$15.52 adjusted for fringe benefits and overhead multiplied by the 2.7 million workers reported for North American Industry Classification System code 62: Health Care and Social Assistance (including private, State, and local government hospitals). Adding 100% for fringe benefits and overhead to the \$15.52 equals \$31.04. Multiplying the pay rate by half the number of support and administrative personnel equals \$42.6 million.

The 2013 BLS data for North American Industry Classification System pharmacies and drugstores reports a total workforce of 708,660 workers. As with the analysis for State employees, we must remove the 348,190 health care workers who are already counted in our training costs analysis of the health care workforce. To avoid

double counting training costs for these occupations, we removed them from the count of the pharmacy workforce. (The entities that employ these workers will still bear the cost for training them.) Their median weighted wage is \$17.22, which is derived from BLS data for medical pharmacy personnel, and the cost associated with an hour of their time is \$34.44 after adjusting for overhead and benefits. We estimate \$6.0 million in costs for training half of these medical pharmacy personnel.³²⁶

For the 360,470 non-medical pharmacy personnel, their weighted median hourly rate for pharmacy employees is \$11.87, which is derived from BLS data for non-medical pharmacy personnel. After adjusting for overhead and benefits, the cost of one hour of time in this category is \$23.74. We estimate \$4.3 million in costs for training half of these non-medical pharmacy personnel.

For the 3,040 navigators, we lack data to determine their wages. As a proxy, we use the wage rate for medical and health service managerial staff, with a median hourly pay rate of \$44.62. Adding 100% for fringe benefits and overhead gives us an adjusted hourly wage of \$89.24. We estimate \$0.1 million in costs for training half of these navigators.

For the remaining entities for which we cannot use BLS data, we must use the industry payroll and employment Census data. To arrive at an estimate of the cost of time for training employees of health insurance issuers and State health and Medicaid agencies, we must divide the total annual payroll reported for these entities by the total number of employees and divide that number by the annual hours paid (2,080 hours), adjusted for fringe benefits and overhead.

For workers employed by the issuers participating in the Health Insurance Marketplaces, it was necessary to determine the hourly wage rate for workers employed in small and large issuers as we have described them above. The total number of workers in small entities (fewer than 500 workers) is 27,269 and the annual payroll is \$1.68 billion. The average wage per employee is \$61,895. Using the 2,080 hours for the annual number of work hours, we obtain an hourly rate of \$29.76.

³²⁶ Determining the cost to train employees other than pharmacists and medical staff who work in pharmacies requires use of the Bureau of Labor Statistics industry data for North American Industry Classification System. These data show that for 2013, 348,380 medical practitioners, technologists and medical support staff were employed in pharmacies and drug stores. U.S. Dep't of Labor, Bureau of Statistics, Occupational Employment Statistics, *supra* note 316.

Assuming that the payroll amounts reported in the Census data do not include fringe benefits and overhead, we add 100% to the hourly rate to yield \$59.51 per hour. Multiplying this amount by half of the 4,454 employees in small issuers equals \$132,540 in training costs.

The total number of employees employed by large issuers (500 or more) is 415,017 and the annual payroll is \$30.8 billion. The average annual wage is \$74,219. Dividing this figure by 2,080 hours yields an hourly wage rate of \$35.68. Multiplying by 100% for fringe benefits and overhead yields \$71.36. Multiplying this amount by 50% of the 87,400 workers equals slightly more than \$3.12 million in training costs.

For State government workers employed in welfare, health, and hospital services, we divided the total number of workers the 2012 Annual Census Bureau reported (873,289

employees) into the monthly payroll reported for the period (\$3,774,775,691).³²⁷ On an annual basis, the average salary per employee equals \$51,870. The hourly rate equals \$24.94 and multiplied by 100% for fringe benefits and overhead yields \$49.87 per worker for training costs.

In the State Medicaid Operations Survey: Second Annual Survey of Medicaid Directors, States reported the median number of full-time Medicaid employees is 421. Using this number multiplied by the 53 Medicaid agencies in the 50 States, the District of Columbia, Puerto Rico, Guam, and the other territories, we added 22,313 workers to the total of health and hospital workers reported in the Census data, bringing the total number of workers in covered State government entities to 553,564. We then subtracted the 442,680 medical personnel we accounted for in the training costs for all

health care personnel and therefore were considered to be duplicative of the medical personnel previously counted in our analysis of medical staff workforce (occupations 29–1000, 29–2000 and 31–0000). This left a net of 110,884 State employees receiving training. Taking half of this number and multiplying it by \$49.87 equals a training cost of slightly more than \$2.76 million.

Although we removed the cost of training the 442,680 medical personnel from the State training cost analysis to avoid double counting training costs, the cost of training half the medical staff may still fall to the States where they are employed. We estimate the cost to train State medical personnel to be approximately \$11.1 million.³²⁸

As noted above, total familiarization costs are estimated to be \$49.1 million. The following table summarizes the training costs we estimate for this rule.

TABLE 4—TOTAL TRAINING COSTS

	Number of entities/workers	Cost (millions)
Training preparation costs (\$125/entity)/entity	* 275,002	\$34.4
Health care staff and managers training	* 7,214,862	326.9
Small Issuers in the Health Insurance Marketplace SM training	2,414	0.1
Large issuers in the Health Insurance Marketplace SM training	43,700	3.1
Navigators	1,399	0.1
State health, hospital and Medicaid worker training	55,442	2.8
Pharmacy worker training	180,235	4.3
Total	7,498,052	371.7

* Not included in column total.

C. Notification and Other Procedural Requirements

1. Designation of Responsible Employee and Adoption of Grievance Procedures

Pursuant to the regulations implementing Section 504, recipients of Federal financial assistance with 15 or more employees are required to designate a responsible employee to coordinate compliance with respect to nondiscrimination requirements and to have grievance procedures to address complaints of discrimination under this law. Of the 275,002 covered entities, approximately 15% employ more than 15 employees, resulting in approximately only slightly more than 41,250 covered entities being required to have grievance procedures and designate a responsible official. Thus, all recipients of Federal financial assistance with 15 or more employees are already expected to have in place

grievance procedures and a designated employee to coordinate their compliance responsibilities. The rule standardizes the requirement to designate a responsible employee and adopt grievance procedures across all bases of discrimination prohibited under Section 1557.

To implement the rule, a recipient of Federal financial assistance could increase the responsibilities of an already-designated employee to handle compliance with the rule's nondiscrimination requirements. In addition, a recipient of Federal financial assistance could increase the scope of existing grievance procedures to accommodate complaints of discrimination under all bases prohibited under Section 1557. The costs associated with these requirements are the costs of training the designated employee on the employee's increased responsibilities and the costs associated

with modifying the existing grievance procedures to reflect the additional bases of race, color, national origin, sex, and age. Here we are referring to employee training to perform their specific enforcement responsibilities, not one-time training in the provisions of the final rule described in the training section above. We also note that grievance officials will probably receive specific training on their new responsibilities and that covered entities will probably provide this additional training and absorb the costs, which are expected to be de minimis. Many covered entities already may be using their existing grievance procedures to address the additional cases covered under Section 1557.

State-based Marketplaces are required to designate an employee to handle compliance responsibilities and to adopt grievance procedures under the ADA. The duties of the employee and

³²⁷ U.S. Census Bureau, Government Employment & Payroll, <http://www.census.gov/govs/apes/> (last visited May 3, 2016).

³²⁸ We calculated the cost of training the medical personal using the weighted median hourly rate,

\$47.22, multiplied by the 446,210 medical staff identified as employed in State governments.

the grievance procedures could be modified to reflect all the bases covered under Section 1557.

We have not estimated the additional costs of training grievance officials on their individual enforcement responsibilities, but we believe such cost would be absorbed in general training costs of all employees on their job responsibilities. Costs associated with modifying existing grievance procedures are covered in the section of the analysis on enforcement.

2. Notice Requirement

The implementing regulations of Title VI, Section 504, Title IX, and the Age Act require recipients of Federal financial assistance and, in the case of Section 504, the Department, to notify individuals that recipients (and, under Section 504, the Department) do not discriminate. The content of the nondiscrimination notices varies based on the applicable civil rights law.

The final rule harmonizes notification requirements under Title VI, Section 504, Title IX and the Age Act, and standardizes the minimum information for a notice. The final rule also requires initial and continuing notification of individuals. OCR drafted a sample notice (located in Appendix A to Part 92) in English that meets the requirements and will translate that notice into 64 additional languages, in advance of the effective date of this rule. Covered entities have discretion to use the OCR sample notice or their own notice, if preferred, and to post the notice in non-English languages.

As all Section 1557 covered entities will need to create or update an existing notice of nondiscrimination, all covered entities can discharge their responsibilities under § 92.8(a) by replacing their current notices with the sample notice developed by OCR (found in Appendix A), available to all covered entities pursuant to § 92.8(c). Using the sample OCR notice means that covered entities will not have to compose their own notices; we expect nearly all covered entities will use the sample OCR notice.

All covered entities will incur costs, however, to implement § 92.8(a) of the final rule, which requires “initial and continuing” notification. Such notification is expected to involve:

- Downloading the notice from the OCR Web site;
- Printing copies of the notice for posting;
- Posting hard copies of the notice in public spaces of the office or facility; and
- Posting the notice on the entity’s Web site, if it has one.

While many costs to comply with this rule are incurred at the entity level, the costs of downloading, printing, and posting the notice are incurred at the establishment level. There are approximately 275,000 covered entities covered by this final rule. According to 2012 Census data, these covered entities are associated with 405,534 establishments. We estimate that a clerical worker at each establishment would spend an average of one minute downloading the notice from the OCR Web site, an average of one minute printing copies of the notice for posting, an average of five minutes posting hard copies of the notice in public areas, and an average of ten minutes total between preparing the OCR notice for posting on the facility’s Web site and posting the notice on the Web site. This implies that the estimated cost associated with posting is \$8.79 ($\$31.04 \text{ per hour} \times 17 \text{ minutes} \times 1 \text{ hour per } 60 \text{ minutes}$) per establishment, which implies that the total estimated cost associated with this requirement is \$3.6 million ($\$8.79 \text{ per establishment} \times 405,534 \text{ establishments}$).

Covered entities will need to update their significant publications and significant communications to include the new notice. However, as noted above, OCR is allowing entities to exhaust their current publications, rather than do a special printing of the publications to include the new notice. When covered entities restock their printed materials, they will be expected to include in those printed materials the notice that OCR will provide with this final rule.

Because we are permitting covered entities to exhaust their existing stock of publications with the current notices before using the new notice, we conclude that the notice requirement imposes no resource costs related to including updated notices in the publications.

Section 92.8 provides covered entities discretion to post the OCR sample notice of nondiscrimination in non-English languages, which can include languages that differ from OCR’s list. In addition, covered entities can draft and translate their own notice in however many languages they choose, if they prefer.

We examined CMS contractual cost for translating a one page notice into 13 languages. It was \$1,000 per page. Based on this figure, we expect total costs to the government to be limited to \$64,000 to translate the notice into 64 languages and place the translated notices on OCR’s Web site. The sample notice is one page long. In addition, we expect total costs to the government for

translating the statement of nondiscrimination for small-size publications to be \$50 for each of the 64 languages. We count the nondiscrimination statement as .05 pages long.

Although not required, we expect that many covered entities would choose to post the OCR-provided notice in one or more non-English languages on their Web sites, in their physical office space, and in certain publications they may have. We do not know how many covered entities would take this action or how many non-English language versions of the notice they would choose to post, or where they would make the non-English versions of the notice available.

Section 92.8 requires covered entities to publish taglines indicating the availability of language assistance services in the top 15 languages of the relevant State or States. Before the effective date of the rule, OCR will make these taglines available electronically in 64 languages; therefore, there will be no burden to the covered entity other than the cost of printing and posting these taglines, as described above with respect to the notice. We are uncertain of the exact volume of taglines that will be printed or posted, but we estimate that covered entities will print and post the same number of taglines as notices and therefore the costs would be comparable to the costs for printing and disseminating the notice, or \$3.6 million. The costs to the Federal government for translating the taglines will be approximately \$50, based on counting each tagline as being .05 pages long. We estimate that the combined costs of printing and distributing notices, nondiscrimination statements, and taglines will be \$7.1 million for entities and \$70,400 for the Federal government.

D. Meaningful Access for Individuals With Limited English Proficiency

In the proposed rule, we said that § 92.201, which effectuates Section 1557’s prohibition of national origin discrimination as it affects individuals with limited English proficiency, does not pose any new burden on covered entities. This is because, with regard to recipients of Federal financial assistance, the proposed rule adopted recipients’ existing obligations under Title VI to take reasonable steps to provide meaningful access to individuals with limited English proficiency and codified the standards consistent with long-standing principles from the HHS LEP Guidance regarding the provision of oral interpretation and written translation services. However,

we anticipate that, as a result of issuance of the final rule, covered entities may choose to take one extra step: To develop and implement a language access plan, in order to ensure that they provide meaningful access to individuals with limited English proficiency. We have thus revised our cost estimates, for the final rule, as shown below, to reflect our assumption that 50% of the covered entities will choose to develop a language access plan.

Although Title VI does not apply to the Department, Executive Order 13166 “Improving Access to Services for Persons with Limited English Proficiency” has applied to HHS for nearly 15 years.³²⁹ This Executive Order requires Federal departments to develop and implement a plan, consistent with the HHS LEP Guidance, to ensure that persons with limited English proficiency can meaningfully access the Department’s programs and activities. HHS adopted a Language Access Plan in 2000, and updated it in 2013, to provide individuals with limited English proficiency meaningful access to HHS-conducted programs and activities, including Federally-facilitated Health Insurance Marketplaces.³³⁰ Because the final rule does not impose duties beyond the Department’s existing obligation under the Executive Order, the rule imposes no new burden on the Department.

In order to estimate the costs of developing a language access plan for recipients of Federal financial assistance, we assume that developing a plan requires approximately three hours of medical and health service managers staff time for the first year, and then an average of one hour of medical and health service managers staff time per year to update the plan in subsequent years. We based our assumption of three hours on feedback from covered entities included in our pre-award compliance review program. This program reviews civil rights compliance of 2,000 to 3,000 health care provider applicants for Medicare Part A per year.

The health care providers that receive Medicare Part A funds already have to develop a written language access plan as a requirement of participation in the Medicare Part A program. Thus, we can reduce the number of covered entities from having a new burden of developing a language access plan. CMS reports data on Medicare hospital spending per claim which identifies 3,209 unique hospitals, which suggests that at least

3,209 hospitals participate in Medicare Part A. As discussed previously, Census data reports that there are a total of 3,688 hospital firms in the United States. Census data reports that there are 6,741 establishments associated with these firms, which in turn suggests that at least 47.6% (3,209/6,741) participate in Medicare Part A. Census data also reports that there are 8,623 nursing care facility entities in the United States. For the purpose of this analysis, we assume that 47.6% of hospitals and nursing care facilities participate in Medicare Part A. Applying 47.6% to all hospitals and nursing care facilities, we estimate that 5,861 entities (47.6% × 3,688 hospital entities (firms) + 47.6% × 8,623 nursing care facility entities) covered by this rule participate in Medicare Part A. This implies that 269,141 entities (firms) will potentially make changes and develop a language access plan as a response to the rule. We arrived at the 269,141 number by subtracting the number of entities participating in Medicare Part A (5,861) from the total number of entities (275,002). We estimate that 50% of these entities will make these changes. Taken together, these assumptions imply that the total cost of the development of language access plans will be approximately \$36.0 million (269,141 entities × 50% of entities × 3 hours per entity × \$89.24 per hour) in the first year and approximately \$12.0 million (269,141 entities × 50% of entities × 1 hour per entity × \$89.24 per hour) per year in subsequent years.

We received a number of comments stating that developing a language access plan imposes a cost burden on covered entities. We revised the proposed rule to include cost estimates, in this final rule, for the development of language access plans, as outlined in the paragraph above. We also received comments that providing interpreters imposes a heavy burden on covered entities. The obligation to provide interpreters as part of taking reasonable steps to provide meaningful communication with individuals with limited English proficiency has been a requirement under Title VI for many years. As a result of developing a language access plan, a covered entity might find increased efficiencies in providing language assistance services. Another covered entity might incur extra costs for the provision of language assistance services on more occasions. We are unable to estimate at this point how many covered entities will incur extra costs or the extent of such costs or the savings realized in increased efficiencies. We anticipate that the potential increased efficiencies and

increased costs may offset each other to some degree. Thus, we do not believe this rule will impose a greater burden regarding the costs of language assistance services than exist under Title VI.

E. Nondiscrimination on the Basis of Sex

Section 1557 prohibits discrimination on the basis of sex in certain health programs and activities. When providing services, including access to facilities, covered entities must provide individuals with equal program access on the basis of sex, and covered entities are required to treat individuals in a manner consistent with their gender identity.

Title IX applies to educational institutions. Therefore, medical schools, nursing programs, and other health education programs were already prohibited from discriminating on the basis of sex prior to the enactment of Section 1557. Under Section 1557 and this regulation, health insurance issuers receiving Federal financial assistance, hospitals, clinics and other health facilities, HHS health programs and activities, and Title I entities, along with the staff and practitioners working in these health programs, are now similarly prohibited from discriminating on the basis of sex.³³¹ This section discusses the costs associated with the prohibition of discrimination on the basis of sex in the rule, taking into account the existing environment, including legal authorities, that addresses equal access on the basis of sex.

Covered entities that provide or administer health services or health insurance coverage are covered by the prohibition of discrimination on the basis of sex. The costs that we anticipate that covered entities would incur relate to: (1) Training; (2) enforcement; (3) the posting of the notice; (4) the revision of policies and procedures; and (5) some costs associated with changes in discriminatory practices. This section discusses costs related to changes in policy and procedures and potential changes in discriminatory practices.

³³¹ Consistent with OCR’s enforcement of other civil rights authorities, the proposed definition of “Federal financial assistance” under the regulation does not include Medicare Part B, which means that physicians receiving only Medicare Part B payments are not covered under the regulation. However, because almost all physicians receive payments from other Department programs such as Medicaid or Medicare meaningful use payments, we believe that there are very few physicians excluded from these provisions. See *supra* pt. I. C. 1.

³²⁹ Exec. Order No. 13166, 65 FR 50121 (2000).

³³⁰ U.S. Dep’t of Health & Human Servs., Language Access Plan, *supra* note 186.

1. Costs for Entities Providing or Administering Health Services

The rule would not invalidate specialties that focus on men or women, *e.g.*, gynecology, urology, etc. Nor would providers have to fundamentally change the nature of their operations to comply with the regulation. For example, the rule would not require a provider that operates a gynecological practice to add to or change the types of services offered in the practice.

Under the sex discrimination prohibition, however, providers of health services may no longer deny or limit services based on an individual's sex, without a legitimate nondiscriminatory reason. Although a large number of providers may already be subject to state laws or institutional policies that prohibit discrimination on the basis of sex in the provision of health services, the clarification of the prohibition of sex discrimination in this regulation, particularly as it relates to discrimination on the basis of sex stereotyping and gender identity, may be new. We anticipate that a large number of providers may need to develop or revise policies or procedures to incorporate this prohibition. For example, if a hospital or other provider has specific protocols in place for domestic violence victims, but engages that protocol only for women, the provider would have to revise its procedures to require that protocol for all domestic violence victims regardless of sex. A provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to provide the procedure for transgender individuals in the same manner it provides the procedure for other individuals.

a. Developing or Revising Policies and Procedures

We assume that it will take, on average, three to five hours for a provider to develop or modify policies and procedures concerning sex discrimination. We are selecting four hours, or the midpoint of this range, for our analysis. We further assume that an average of three of the hours will be spent by a mid-level manager equivalent to a front-line supervisor (Occupation code 43–1011), at a cost of \$48.84 per hour after adjusting for overhead and benefits, and an average of one hour will be spent by executive staff equivalent to a general and operations manager (Occupation code 11–1021), at a cost of \$93.54 per hour after adjusting for overhead and benefits. We further

assume that 75% of covered entities will need to develop or modify policies and procedures, given that some proportion of health care providers already prohibit sex discrimination based on State law or institutional policies prohibiting discrimination generally. The total cost for the estimated 206,252 covered entities to make their policies and procedures consistent with the regulatory prohibition on discrimination on the basis of sex is estimated to be approximately \$49.5 million, which we assume is divided evenly between the first two years of compliance.

The above estimates of time and number of entities that would have to revise their policies under the regulation is an approximate estimate based on general BLS data. Due to the wide range of types and sizes of covered entities, from complex multi-divisional hospitals to small neighborhood clinics and physician offices, the above estimates of time and number of entities that would have to revise their policies under the regulation is difficult to calculate.

b. Ending Discriminatory Practices

For providers that discriminate on the basis of sex in violation of the rule, some changes in behavior or action would be necessary to come into compliance. We anticipate some change in the patient population for which a particular provider provides care or the extent of services provided. However, the infrastructure and protocols for providing services or treatment are already in place; providers would simply have to start providing those existing services in a nondiscriminatory manner to individuals regardless of sex. For example, a provider could not refuse to treat a patient for a cold or a broken arm based on the patient's gender identity. Similarly, if the provider is accepting new patients, it must accept a new patient request from a transgender individual and cannot decline to accept a transgender individual in favor of a person who is not transgender.

However, the rule does not impose a burden on covered entities with respect to the number of patients treated. The rule does not require a covered entity to change the total number of patients it sees or to treat more patients than it currently accepts. Providers may continue to treat the same number of patients that were accepted prior to the issuance of this final rule, but they must do so in a nondiscriminatory manner. Thus, for example, if a provider is not accepting new patients, the provider does not have to accept a new patient request from a transgender individual.

We anticipate that the costs associated with these types of changes would be de minimis.

Moreover, costs associated with administering care or treating a new patient generally would be offset by the reimbursement received by the provider for providing the care, in the same way the provider gets paid for existing care or treatment of patients. Thus, for example, for the hospital or other provider that needs to revise its protocol for domestic violence to require that protocol for all domestic violence victims regardless of sex, rather than just women, there would be little to no net increase in costs for treating men because the hospital or provider would be paid for its services in the same way it is paid to treat women.

2. Costs for Entities Providing or Administering Health Insurance Coverage

The ACA, including Section 1557, changed the health care landscape for millions of people by instituting protections against sex discrimination in the provision of health care and health insurance coverage. Prior to the ACA, it was standard health insurance practice to treat women differently in premium pricing and coverage of benefits,³³² while transgender individuals frequently experienced discrimination when seeking coverage for treatment.³³³

The ACA addresses inequitable treatment by health plans based on sex in multiple ways. The regulations from CMS implementing the ACA prohibit Title I entities³³⁴ and most health insurance issuers³³⁵ from

³³² See Adelle Simmons, Katherine Warren, & Kellyann McClain, U.S. Dep't of Health & Human Servs., Office of the Assistant Sec'y for Planning and Eval., ASPE Issue Brief, *The Affordable Care Act: Advancing the Health of Women and Children* (Jan. 2015), <https://aspe.hhs.gov/pdf-report/affordable-care-act-advancing-health-women-and-children>; U.S. Dep't of Health & Human Servs., Women and The Affordable Care Act, <http://www.hhs.gov/healthcare/facts-and-features/fact-sheets/women-and-aca/index.html> (last visited May 3, 2016).

³³³ See Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010), <http://www.lambdalegal.org/publications/when-health-care-isnt-caring>.

³³⁴ 45 CFR 155.120(c)(1)(ii) prohibits a Health Insurance MarketplaceSM from discriminating based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.

³³⁵ 45 CFR 147.104(e) prohibits health insurance issuers in non-grandfathered individual, small and large group markets from employing benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, gender

Continued

discriminating based on sex, sexual orientation, and gender identity, in addition to other bases. These market-wide provisions are applicable to health insurance issuers both on and off the Health Insurance MarketplaceSM, which includes qualified health plan issuers³³⁶ and health insurance issuers providing non-grandfathered coverage in the individual and group markets outside of the Health Insurance MarketplaceSM.³³⁷

In addition, the ACA prohibits many health insurance issuers from charging higher premiums based on sex;³³⁸ failing to provide essential health benefits that greatly impact women, such as maternity care;³³⁹ failing to cover preventive services that are necessary for women's health, such as mammograms;³⁴⁰ and denying benefits based on pre-existing conditions³⁴¹ or health factors,³⁴² many of which affect women's health, such as a history of a Caesarian section or a history of domestic violence.³⁴³ Thus, health insurance issuers and the Health Insurance Marketplaces have already had to expand access to women and lesbian, gay, bisexual and transgender (LGBT) individuals under these health insurance market reforms, independent of Section 1557. The existence of these other provisions circumscribes cost burdens on Health Insurance Marketplaces and issuers in the ACA-compliant individual and small group markets that are recipients of Federal financial assistance that are imposed by the prohibition of sex discrimination in the rule.

Section 92.207 (Nondiscrimination in health insurance and other health

identity, sexual orientation, expected length of life, degree of medical dependency, quality of life, or other health conditions. 45 CFR 156.200(e) prohibits a qualified health plan issuer from discriminating on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation. 45 CFR 156.125(a) prohibits issuers that provide essential health benefits from using benefit designs that discriminate based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. 45 CFR 156.125(b) requires issuers that provide essential health benefits to comply with 45 CFR 156.200(e).

³³⁶ 45 CFR 147.104(e), 156.200(e) and 156.125(a)–(b) are applicable to qualified health plan issuers.

³³⁷ 45 CFR 147.104(e) is applicable to non-grandfathered coverage in the individual, small and large group markets. 45 CFR 147.150(a) incorporates essential health benefits requirements (and implementing regulations at 45 CFR 156.200(e) and 156.125(a)–(b)) for non-grandfathered coverage in the individual and small group markets.

³³⁸ 42 U.S.C.300gg.

³³⁹ *Id.* 18022 (b).

³⁴⁰ *Id.* 300gg–13 (a)(4).

³⁴¹ *Id.* 18001.

³⁴² *Id.* 300gg–4.

³⁴³ *Id.* 300gg–4(a)(7); ASPE Issue Brief, *supra* note 332.

coverage) of the rule prohibits discrimination on the basis of sex by a covered entity providing or administering health insurance or other health coverage. As noted, many of the same covered entities subject to Section 1557, including Health Insurance Marketplaces and health insurance issuers in the individual and small group markets that are recipients of Federal financial assistance, are also subject to existing nondiscrimination provisions in CMS regulations. Although the CMS regulations complement and do not replace Section 1557 or this part, the existing nondiscrimination requirements applicable to health insurance issuers and Health Insurance Marketplaces have made these entities aware that they are not permitted to discriminate on the basis of sex, sexual orientation, or gender identity, and thus they are familiar with their nondiscrimination obligations under the law. We assume that these covered entities have already taken steps to comply with CMS regulations and so instituted changes in their policies and actions. To the extent these existing obligations overlap with Section 1557 and covered entities have complied with the CMS regulations that prohibit discrimination on the basis of sex, sexual orientation, and gender identity, this rule will impose little or no burden on health insurance issuers and Title I entities to comply with Section 1557's and this part's prohibition on sex discrimination. However, the rule nonetheless imposes some costs.

a. Developing or Revising Policies and Procedures

There may be some incremental burden on issuers and Title I entities in terms of the additional guidance that this rule provides related to sex discrimination, because, in some circumstances, it provides more detail than CMS regulations or guidance. Therefore, covered entities may have an increased burden when incorporating this rule into their existing nondiscrimination policies and procedures. For example, this rule specifies that a categorical coverage exclusion or limitation for all health care services related to gender transition is discriminatory on its face. If a covered entity had not previously understood sex discrimination on the basis of gender identity in this way, the covered entity would have to revise its policies and procedures to provide coverage consistent with this final rule's parameters, which might include revising policies to include gender transition-related care.

However, we note that the number of major U.S. employers providing transgender-inclusive health care coverage has been increasing, from 0 in 2002, to 49 in 2009, 278 in 2013, 336 in 2014, 418 in 2015, and at least 511 in 2016.³⁴⁴ This indicates that plans that offer transgender-inclusive health care are becoming readily available as models for issuers that may not offer such care, limiting their costs in developing or revising policies and procedures for compliance.

Similar to the estimate for providers of health services, we assume that it will take, on average, three to five hours for issuers of health insurance coverage to develop or modify policies and procedures concerning sex discrimination. We are selecting four hours, or the midpoint of this range, for our analysis. We further assume that three of the hours will be spent by a mid-level manager, at a salary, with fringe benefits and overhead of \$57.60 per hour,³⁴⁵ and one hour will be spent by executive staff, at a salary, with fringe benefits and overhead of \$122.15 per hour. Based on our best estimate of industry compliance with CMS regulations, we further assume that one-third or 33% of health insurance issuers will need to develop or modify policies and procedures. Based on an unduplicated count of issuers, we previously identified 180 issuers in the Marketplaces (including Federally-facilitated Marketplaces). One third of this number equals 60 issuers that we estimate would need to revise policies to address the prohibition of sex discrimination in this regulation. The costs to issuers to revise policies and procedures to provide coverage consistent with this rule's parameters equal 60 issuers multiplied by \$295 for a one-time cost of \$17,700.

b. Ending Discriminatory Practices

In addition to the cost some covered health insurance providers may have for revising policies and procedures to comply with the rule, such providers may also incur a de minimis cost related to the cost of coverage. In this regard, we note that the April 2012 California

³⁴⁴ Human Rights Campaign, Corporate Equality Index, *Rating American Workplaces on Lesbian, Gay, Bisexual and Transgender Equality*, <http://www.hrc.org/campaigns/corporate-equality-index> (last visited May 3, 2016).

³⁴⁵ U.S. Dep't of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2015 National Occupational Employment and Wage Estimates by ownership, http://www.bls.gov/oes/2014/may/oes_nat.htm (last visited May 3, 2016) (using data for First-Line Supervisors of Office and Administrative Support Workers and General and Operations Managers for the health insurance industry).

Department of Insurance Economic Impact Assessment on Gender Nondiscrimination in Health Insurance found that covering transgender individuals under California's private and public health insurance plans would have an "insignificant and immaterial" impact on costs.³⁴⁶ This conclusion was based on evidence of low utilization and the estimated number of transgender individuals in California. The transgender population of California was estimated to range between 0.0022% and 0.0173%.³⁴⁷ The study revealed that, contrary to common assumptions, not all transgender individuals seek surgical intervention, and that gender-confirming health care differs according to the needs and pre-existing conditions of each individual.³⁴⁸ Despite expecting a possible spike in demand for benefits due to former or current unmet demand, the California Insurance Department concluded that any increased utilization that might occur over time is likely to be so low that any resulting costs remain actuarially immaterial.³⁴⁹ Additionally, issuers in California that established premium surcharges after enactment of California's Gender Nondiscrimination in Health Insurance Law subsequently eliminated them because they found they did not spend the extra funds generated.³⁵⁰

Two other studies also support the conclusion that the cost is de minimis for entities providing or administering health insurance coverage to come into compliance with this rule's provision of nondiscrimination on the basis of sex. One is a 2013 Williams Institute study of 34 public and private employers, and the second consists of cost projections of providing transition-related health-care benefits to members of the military.

The first of these two studies, a 2013 study of 34 employers that provided nondiscriminatory health care coverage, found that providing transition-related benefits to treat gender dysphoria had "zero to very low costs."³⁵¹

The second study, published in the *New England Journal of Medicine*,

projected that the cost for providing transition-related health care benefits to members of the military would result in an annual increase of 0.012% of health care costs, "little more than a rounding error in the military's \$47.8 billion annual health care budget."³⁵² Based on the California and two other studies discussed above, we estimate that providing transgender individuals nondiscriminatory insurance coverage and treatment will impact a very small segment of the population due to the fact that the number of transgender individuals (and particularly those who seek surgical procedures in connection with their gender transition) in the general population is small, and consequently will have de minimis impact on the overall cost of care and on health insurance premiums.³⁵³

F. Accessibility of Electronic and Information Technology

Although Section 1557 requires covered entities to ensure that the health programs, services, and activities provided through electronic and information technology are accessible to individuals with disabilities, all covered entities affected by Section 1557 already have these obligations under Section 508, Section 504 or the ADA.

1. HHS Health Programs and Activities, Including the Federally-Facilitated Marketplaces

Section 508 requires that electronic and information technology developed, procured, maintained, or used by Federal agencies be accessible for individuals with disabilities (both members of the public and Federal employees). Section 504 also establishes general obligations for Federal agencies to make their programs that are provided through electronic and information technology accessible to individuals with disabilities. Both Section 504 and Section 508 were in place before the passage of the ACA. There is, therefore, no additional burden under Section 1557 for HHS health programs, including the Federally-facilitated Marketplaces, as the Section 1557 requirements are consistent with the obligations these programs already have under Section 504 and Section 508.

2. Recipients of Federal Financial Assistance From HHS and Title I Entities

Section 504 also establishes general obligations for entities receiving Federal financial assistance to make their programs, services, and activities provided through electronic and information technology accessible to individuals with disabilities. The ADA imposes similar accessibility requirements on covered entities. This rule thus imposes no additional burden on recipients of Federal financial assistance from HHS because Section 1557 is consistent with existing standards these entities are already obligated to meet under the ADA and Section 504. Title I entities have no Section 1557 burden with respect to this proposed requirement, as the Title I entities must already be compliant with the ADA, which is consistent with the Section 1557 accessibility standards.

G. Enforcing the Rule

After grievances are filed with covered entities or complaints are filed with OCR, there are associated costs to investigate and resolve those grievances and complaints. We believe the following costs result from enforcement of the Section 1557 regulation:

- Costs to covered entities for modifying and implementing grievance procedures to cover grievances filed under Section 1557.
- Costs to OCR for reviewing and investigating complaints, monitoring corrective action plans, and taking other enforcement actions against covered entities.

In the analysis below, we estimate the aggregate costs of these enforcement procedures, and analyze the costs to covered entities separately from the costs to OCR.

1. Costs to Covered Entities

Federal civil rights laws that were in place before the enactment of Section 1557 apply to entities that receive Federal financial assistance. Entities subject to those laws are already required to have in place established grievance procedures to address complaints of disability discrimination and complaints of sex discrimination in education programs. We anticipated that additional costs arising from the expansion of the grievance process to cover all bases included in Section 1557, including race, color, national origin, and age, as well as sex discrimination in health care, could impose additional costs on covered entities. We assumed a slight increase in the number of grievances filed, and a

³⁴⁶ State of Cal., Dep't of Ins., Economic Impact Assessment Gender Nondiscrimination in Health Insurance, (Apr. 13, 2012), <http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf>.

³⁴⁷ *Id.*

³⁴⁸ *Id.* at 8.

³⁴⁹ *Id.* at 9.

³⁵⁰ *Id.* at 6–7.

³⁵¹ The Williams Inst., Cost and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings from a Survey of Employers, at 2 (Sept. 2013), <http://williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf>

³⁵² A. Belkin, "Caring for Our Transgender Troops — The Negligible Cost of Transition-Related Care," 373 New Eng. J. Med. 1089 (Sept. 15, 2015).

³⁵³ State of Cal., Dep't of Ins., *supra* note 346, at 2, 5. Issuers in California that established a premium surcharge to cover the City of San Francisco's expected claim costs eventually eliminated the additional premium because they found their cost assumptions were 15 times higher than actual claims generated.

corresponding increase in time to investigate and resolve these additional grievances.

To compute the anticipated costs for covered entities to enforce the regulation, we looked to OCR data. The current number of civil rights complaints filed annually with OCR is approximately 3,000. Since the passage of Section 1557, OCR's complaint workload has increased slightly, with approximately 15 to 20 unique Section 1557 cases filed each year. If we include another ten cases per year as a result of the promulgation of the regulation, we calculate an increase of 30 cases per year or 1% of the annual caseload of 3,000. We assume the incremental workload will be similar for affected entities and thus will be approximately 1%. We anticipate that within the first five years following the promulgation of the regulation, complaints will initially increase, but then will eventually drop off as covered entities modify their policies and practices in response to the rule. Due to the likelihood that applicable changes will need to be phased in, we assume one half of the annual projected costs for investigating discrimination complaints will be incurred during the first year and three quarters of the annual projected enforcement costs will be spent in the second year and the full amounts in the third through fifth years. Although we have data on OCR's caseload, we have no data on the caseload of affected covered entities.

We assume that as a result of promulgating the regulation, the 41,250 covered entities with 15 or more employees will require an average of an additional 1% of a Full Time Equivalent (FTE) for designated grievance officials to investigate discrimination grievances in years three through five following publication of the final rule, with costs half as large in the first year and costs three quarters as large in the second year. We assume the grievance official's salary is equivalent to that of medical

and health service managers (occupation code 11-9111), who have annual median wages of \$103,680. These assumptions imply costs, after adjusting for fringe benefits and overhead, of \$42.8 million in the first year, \$64.2 million in the second year, and \$85.5 million in years three through five following publication of the final rule.

One comment suggested that litigation costs may also rise as a result of issuance. We assume that the costs of litigation are included in the costs listed in the paragraph above.

The same incremental calculations apply to the workloads of State agencies and the officials working in these agencies. If we assume the same increases in workload at each State agency as discussed previously, and the average mid-level State official salary is \$94,580 (including fringe benefits and overhead), we must multiply \$94,580 by the number of State covered entities.³⁵⁴ To arrive at the number of State covered entities we make the following assumptions:

- We assume that there are 56 Medicaid State agencies;
- We assume that there are 56 State health departments;
- We assume that there are 1,003 State and local government community hospitals;³⁵⁵ and
- We assume that each of 3,143 counties has a county health department that provides direct health services (e.g., immunization clinics) and is accountable to the State Health Department. We assume that each of the county health departments has a designated official for handling grievances.

The total number of State covered entities is 4,252. Multiplying \$94,580 by 4,252 equals \$402.2 million. One percent of this value equals \$4.0 million. This implies costs of \$2.0 million in the first year, \$3.0 million in the second year and \$4.0 million in

subsequent years following the publication of the final rule.

2. Costs to OCR

We considered the various OCR enforcement costs together, based on OCR average salary data presented in its annual budgets. According to the FY 2016 President's Budget, \$28,400,000 and 137 FTEs were requested for Enforcement and Regional Operations, at a cost of approximately \$201,000 per FTE. Of the 137 FTEs, approximately 40 FTEs spend 100% of their investigative time enforcing the civil rights laws.³⁵⁶ If we make the same assumption we did above and assume the same increase in caseload from the issuance of Section 1557 as discussed above, the anticipated increase in number of staff necessary would be approximately 0.4 of an FTE (1% of 40) and would cost approximately \$40,200 in the first year, \$60,300 in the second year, and \$80,400 in subsequent years following the publication of the final rule.

3. Summary of Cost and Phase-In

The table below summarizes the costs attributable to the regulation that covered entities may incur following enactment of the final regulation. We assume that half of the training costs and changes to policies and procedures on the prohibition of discrimination on the basis of sex will be incurred in the first year and the second half will be expended in the second year. For covered entities that will be printing and distributing notices to their patients and policy holders, we assume that all of the estimated printing and distribution costs will be expended in the first year after the effective date of the rule. Familiarization costs, information collection requirements and paperwork burden costs would be incurred within the first year after the effective date of the final regulation. Cost of enforcement, by contrast, will increase over the course of the first five years.

TABLE 5—COST SUMMARY OF THE REGULATION FOLLOWING ENACTMENT OF THIS FINAL RULE
 [Discounted 3% and 7% in millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total/ annualized
Training and Familiarization (undiscounted)	234.9	185.8	0.0	0.0	0.0	420.8
Training and Familiarization (3%)	228.1	175.2	0.0	0.0	0.0	88.1
Training and Familiarization (7%)	219.6	162.3	0.0	0.0	0.0	93.1
Enforcement (undiscounted)	44.8	67.2	89.6	89.6	89.6	381.0
Enforcement (3%)	43.5	63.4	82.0	79.6	77.3	75.5
Enforcement (7%)	41.9	58.7	73.2	68.4	63.9	74.6
Notice Publication (undiscounted)	7.2	0.0	0.0	0.0	0.0	7.2

³⁵⁴ Based on the annual salary of Executive Secretary and Executive Administrative Assistant.

³⁵⁵ American Hospital Ass'n: Fast Facts on US Hospitals, (Jan. 2016), <http://www.aha.org/research/rc/stat-studies/101207fastfacts.pdf>.

³⁵⁶ This is based on an informal staff estimate.

TABLE 5—COST SUMMARY OF THE REGULATION FOLLOWING ENACTMENT OF THIS FINAL RULE—Continued
[Discounted 3% and 7% in millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total/ annualized
Notice Publication (3%)	7.0	0.0	0.0	0.0	0.0	1.5
Notice Publication (7%)	6.7	0.0	0.0	0.0	0.0	1.6
Sex discrimination	24.8	24.8	0.0	0.0	0.0	49.5
Policy and Procedure Changes (undiscounted):						
Sex discrimination	24.0	23.3	0.0	0.0	0.0	10.3
Policy and Procedure Changes (3%):						
Sex discrimination	23.1	21.6	0.0	0.0	0.0	10.9
Policy and Procedure Changes (7%):						
Language Access Plan (undiscounted)	36.0	12.0	12.0	12.0	12.0	84.1
Language Access Plan (3%)	35.0	11.3	11.0	10.7	10.4	17.1
Language Access Plan (7%)	33.7	10.5	9.8	9.2	8.6	17.5
Total (undiscounted)	347.7	289.8	101.6	101.6	101.6	942.5
Total (3%)	337.6	273.2	93.0	90.3	87.7	192.5
Total (7%)	325.0	253.2	83.0	77.5	72.5	197.8

Note: Discounted and annualized values take into account the cost of borrowing and paying back funds at hypothetical interest rates to simulate opportunity costs.

This completes our analysis of the costs of the final rule. Next, we examine the benefits that can be expected to accrue as a result of the final rule.

III. Benefits & Transfers

In enacting Section 1557 of the ACA, Congress recognized the benefits of equal access to health services and health insurance that all individuals should have, regardless of their race, color, national origin, age, or disability. Section 1557 brought together the rights to equal access that had been guaranteed under Title VI, the Age Act and Section 504. At the same time, Congress extended these protections and rights to individuals seeking access to health services and health insurance without discrimination on the basis of sex.

This rule implements the provisions of Section 1557. In most respects, the rule clarifies existing obligations under existing authorities, and we have noted in the cost analysis that we do not expect that covered entities will incur costs related to the clarification of those existing obligations in the final rule. As the HHS LEP Guidance³⁵⁷ and regulation implementing Title VI³⁵⁸ indicate, recipients are already required to take reasonable steps to ensure meaningful access to their programs and activities by persons with limited English proficiency. We note that the additional provisions related to serving individuals with limited English proficiency in the final rule may create some additional costs but will also create substantial benefits to patients and providers by improving access to quality care.³⁵⁹

Studies show that individuals with limited English proficiency experience barriers to receiving regular and adequate health care. However, according to the Institute of Medicine, when reliable language assistance services are utilized, patients experience treatment-related benefits, such as enhanced understanding of physician instruction, shared decision-making, provision of informed consent, adherence with medication regimes, preventive testing, appointment attendance, and follow-up compliance.³⁶⁰ Additional intangible benefits may include retention of cultural information, exchange of information, greater satisfaction with care,³⁶¹ and enhanced privacy and autonomy of individuals with limited English proficiency who may have previously had to rely on family members for language assistance.³⁶²

Health service providers also benefit from providing language assistance services for individuals with limited English proficiency. Providers can more confidently make diagnoses, prescribe medications, reach treatment decisions, and ensure that treatment plans are

understood by patients.³⁶³ “Language is also an important tool for clinicians to establish an empathic connection with patients[;]” accordingly, language assistance services benefit both patients and providers alike.³⁶⁴ One study states that ensuring effective communication can also help providers avoid costs associated with “damages paid to patients, legal fees, the time lost when defending a lawsuit, the loss of reputation and patients, the fear of possible monetary loss, and the stress and distraction of litigation.”³⁶⁵ Another study of malpractice claims found that a malpractice carrier insuring in four states paid over \$2 million in damages or settlements as well as over \$2 million in legal fees over a four year period for claims arising from failure to use an appropriate interpreter.³⁶⁶

We have also noted that we expect that the prohibition of sex discrimination in the final rule will generate certain actions and other changes in behavior by covered entities and that these actions and changes will impose costs. These actions and other

Order No. 13166: Improving Access to Services for Persons with Limited English Proficiency (Mar. 2002), p. 20, <https://www.justice.gov/sites/default/files/crt/legacy/2010/12/14/omb-lepreport.pdf>.

³⁶⁰ Brian D. Smedley, Adrienne Y. Stith, Alan R. Nelson, eds., Institute of Medicine, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, Board on Health Science Policy, (2003), pp.142, 191; Report to Congress, *supra* note 359 at 20–22.

³⁶¹ *Id.*

³⁶² Kelvin Quan & Jessica Lynch, *The High Costs of Language Barriers in Medical Malpractice* (2010), p.17, http://www.healthlaw.org/images/stories/High_Costs_of_Language_Barriers_in_Malpractice.pdf.

³⁶³ ASPE, *Caring for Immigrants: Health Care Safety Nets in Los Angeles, New York, Miami and Houston*, (2001), <https://aspe.hhs.gov/execsum/caring-immigrants-health-care-safety-nets-los-angeles-new-york-miami-and-houston>; Elizabeth A. Jacobs, Donald S. Shepard, Jose A. Suaya and Esta-Lee Stone, *Overcoming Language Barriers in Health Care: Costs and Benefits of Interpreter Services*, *Am. J. Public Health* (2004), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448350/>; *Unequal Treatment*, *supra* note 360 at 141.

³⁶⁴ *Unequal Treatment*, *supra* note 360 at 141.

³⁶⁵ *The High Costs of Language Barriers in Medical Malpractice*, *supra* note 362 at 15.

³⁶⁶ Agency for Healthcare Research and Quality, *Improving Patient Safety Systems for Patients With Limited English Proficiency: A Guide for Hospitals* (2012), <http://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf>.

³⁵⁷ 68 FR 47311, 47313 (Aug. 8, 2003).

³⁵⁸ 45 CFR 80.3.

³⁵⁹ Report to Congress, *Assessment of the Total Benefits and Costs of Implementing Executive*

changes in behavior will also result in benefits.

The provisions prohibiting sex discrimination in the ACA increase the affordability and accessibility of health care for women and transgender individuals. However, despite the ACA improving access to health services and health insurance, many women and transgender individuals continue to experience discrimination in the health care context, which can lead to denials of adequate health care and increases in existing health disparities in underserved communities. This continued discrimination demonstrates the need for further clarification regarding the prohibition of discrimination on the basis of sex.

Prior to the enactment of the ACA, insurance companies were allowed to impose higher premiums on women or deny women coverage altogether. If issuers did cover women, they frequently did not cover a number of women's health services, including routine preventive services, such as pap smears or mammograms. Insurance premiums previously could differ by sex, and were often higher for females relative to males. The ACA prohibits differential treatment based on sex, includes maternity coverage in essential health benefits, and requires non-grandfathered plans to cover women's preventive services without copays, among other benefits.

For transgender individuals, a major barrier to receiving care is a concern over being refused medical treatment based on bias against them.³⁶⁷ In a 2010 report, 26.7% of transgender respondents reported that they were refused needed health care.³⁶⁸ A 2011 survey revealed that 25% of transgender individuals reported being subject to harassment in medical settings, and 50% reported having to teach their medical providers about transgender care.³⁶⁹ We received many comments expressing anecdotal evidence of these statistics.

Another potential barrier for transgender individuals to care is covered entities' nondiscrimination policies, which often do not include gender identity. The 2014 Human Rights Campaign Healthcare Equality Index, which evaluates health care facilities' LGBT policies and practices, found that among the 640 hospitals it evaluated, 501 had patient nondiscrimination

policies but of those only 257 had a patient nondiscrimination policy that included both the terms "sexual orientation" and "gender identity."³⁷⁰

Yet another barrier to care for transgender individuals is the process of obtaining health insurance coverage. A study by the Center for American Progress found that transgender individuals have often experienced difficulties when seeking insurance coverage.³⁷¹ Similarly, in 2014, Out2Enroll, a national campaign that serves as a key link between LGBT communities and the ACA by connecting LGBT people with information about their new coverage options, issued findings in a report entitled "*Key Lessons for LGBT Outreach and Enrollment under the Affordable Care Act*."³⁷² The report focuses on the lack of adequate training of Navigator staff when encountering LGBT individuals seeking access to the Health Insurance Marketplaces. A major complaint was that Navigator staff was unaware of the multitude of discriminatory practices and policy restrictions in which issuers engage to deny or restrict coverage of transgender individuals, and that Navigator staff lacked basic knowledge of health issues that are unique to transgender individuals.³⁷³

Ultimately, transgender individuals who have experienced discrimination in the health care context often postpone or do not seek needed health care, which may lead to negative health consequences.³⁷⁴ A study by the National Center for Transgender Equality and the National Gay and Lesbian Task Force found that "one-quarter of the more than 6,400 transgender and gender-nonconforming respondents reported . . . being denied needed treatment[,] . . . being harassed in health care settings[,] . . . [and] postponing medical care because of discrimination by providers."³⁷⁵ We

received several comments echoing these statements, both from individuals citing personal experiences and from entities citing data. This kind of discrimination exacerbates health disparities experienced by the LGBT population, including: higher rates of mental health issues, including depression and suicide attempts; higher risk of HIV/AIDS; higher use of tobacco and other drugs; and higher risk of certain cancers, such as breast cancer, with some portion of the differential potentially attributable to barriers to health care.³⁷⁶

By prohibiting discrimination on the basis of sex, Section 1557 would result in more women and transgender individuals obtaining coverage and accessing health services. Since 2013, the uninsured rate for women has declined, with nearly 9.5 million women gaining health coverage as of 2016.³⁷⁷ Similarly, uninsured rates for LGBT individuals dropped from 34% in 2013 to 26% in 2014.³⁷⁸ While these declines in the rates of the uninsured are attributable to many factors, among these factors may be provisions in the ACA prohibiting discriminatory practices in insurance. We expect that the Section 1557 regulation may contribute to a continued reduction in the number of individuals who are uninsured, although the reduction would be much more modest.

For a representative example, we look to a State of California economic impact assessment of State practices prohibiting gender discrimination in health care, which cites the following benefits:³⁷⁹

1. Reduced violence against affected individuals;
2. Reduced depression and suicide attempts among the affected population; and
3. Overall declines in substance abuse, smoking and alcohol abuse rates, and improvements in mental health among treated individuals in LGBT populations who receive appropriate medical treatment.

Moreover, because discrimination contributes to health disparities, the prohibition of sex discrimination in health care under Section 1557 can help

³⁷⁰ Human Rights Campaign, Healthcare Equality Index 2014, <http://www.hrc.org/reports/hei>.

³⁷¹ Laura E. Durso, Kellan Baker, and Andrew Cray, Center for American Progress Issue Brief: LGBT Communities and the Affordable Care Act Findings from a National Survey, (Oct. 10, 2013), <http://www.preventionjustice.org/wp-content/uploads/2013/10/CAP-LGBT-Messaging-Research.pdf>.

³⁷² Out2Enroll, Key Lessons for LGBT Outreach and Enrollment under the Affordable Care Act (July 24, 2014), http://out2enroll.org/lgbthealthcare/wp-content/uploads/2014/07/O2E_KeyLessons_FINAL.pdf.

³⁷³ *Id.* at 24.

³⁷⁴ Kellan E. Baker, Center for American Progress, Open Doors for All, Sexual Orientation and Gender Identity Protections in Health Care (Apr. 30, 2015), <https://www.americanprogress.org/issues/lgbt/report/2015/04/30/112169/open-doors-for-all/>.

³⁷⁵ *Id.*

³⁷⁶ *Id.*

³⁷⁷ U.S. Dep't of Health & Human Servs., Office of the Assistant Secretary for Planning and Eval., ASPE Issue Brief: Health Insurance Coverage and the Affordable Care Act 201–2016, 2 (Mar. 3, 2016) <https://aspe/hhs.gov>.

³⁷⁸ Kellan Baker, Laura E. Durso, and Andrew Cray, Center for American Progress, Moving the Needle, The Impact of the Affordable Care Act on LGBT Communities, 3 (Nov. 2014), <https://www.americanprogress.org/issues/lgbt/report/2014/11/17/101575/moving-the-needle/>.

³⁷⁹ California Department of Insurance, *supra* note 346, at 10–12.

³⁶⁷ Lambda Legal, *supra* note 333 at 12–13.

³⁶⁸ *Id.* at 10.

³⁶⁹ National Center for Transgender Equality and National Gay and Lesbian Task Force, Injustice at Every Turn: A Report of the National Transgender Discrimination Survey, 5–6 (2011), <http://www.thetaskforce.org/>.

reduce health disparities. While it is not possible to quantify the benefits of the reduction in health disparities, the benefits would include more people receiving adequate health care, regardless of their sex, including gender identity.

The health and longevity benefits discussed above as potential effects of this rule assume additional or higher-quality medical services are provided to affected individuals. These services would be associated with costs (which we lack data to estimate). As mentioned in the earlier discussion of actuarial risk, to the extent that changes in insurance premiums do not alter how society uses its resources, the final rule would result in transfers between members of society, rather than social costs or benefits. In addition to women and transgender individuals, health service providers and the Federal government could also be recipients of these transfers. For example, in 2013, \$53.3 billion was paid to offset uncompensated care, of which the Federal government paid for approximately \$32.8 billion.³⁸⁰ Based on estimated coverage gains in 2014, uncompensated care costs are expected to continue to fall substantially following continued major insurance coverage expansions, including coverage expansions through the Health Insurance MarketplaceSM.³⁸¹ While issuance of the Section 1557 regulation is not a factor in this projection, we believe that the Section 1557 regulation will likewise contribute to a decrease in payments by the Federal government for uncompensated care by promoting an increase in the number of individuals who have coverage when they receive care.

Aside from the specific benefits and transfers that women and transgender individuals, and the health care community can be expected to gain from the enactment of the regulation, there are additional benefits that are intangible and unquantifiable that derive from providing equal access to health care for all.

IV. Alternatives Considered

In the course of developing this regulation, OCR considered various alternatives. Some of those alternatives are discussed in the preamble. A discussion of alternatives cannot cover all alternatives considered by OCR. The following alternatives are meant to be a representative sample to show how burden reduction was a major consideration in constructing the standards in this regulation.

The first option is no new regulatory action. We did not select this option because we believe the regulation provides substantial benefits to society, net of the costs. We received a comment suggesting that we consider either writing a more informative than prescriptive regulation or delaying the regulation, based on a possible trend of increased voluntary compliance by health care agencies with nondiscrimination statutes. OCR's current experience, however, points to the importance of and need for a prescriptive regulation. OCR provides education and information on the civil rights statutes and regulations, conducts technical assistance and outreach to promote compliance, and is developing training materials to provide information and technical assistance on this rule. However, OCR has found that providing information and outreach is not sufficient to ensure nondiscrimination in health care programs and activities. OCR continues to receive and resolve many complaints of discrimination and to hear of ongoing discrimination through outreach and communications with stakeholders. The regulation will inform stakeholders of their rights so that affected individuals know that they can seek OCR's assistance, and will provide clarity for covered entities, limiting uncertainty and promoting compliance. In addition, the majority of the comments from the public in response to the proposed rule favored issuance of a regulation.

OCR considered requiring covered entities to provide separate notices, covering separate content, *e.g.*, separate notices on the requirements concerning the provision of meaningful access for individuals with limited English proficiency, requirements concerning effective communication for individuals with disabilities, and policies on nondiscrimination. To reduce the burden on covered entities, OCR rejected this option in favor of a comprehensive single-notice requirement. We are also permitting entities to combine the Section 1557 notice with other notices that the entities may be required to post.

OCR decided to further reduce the burden imposed on covered entities by the notice requirement by making available a sample notice, located in Appendix A. OCR allows covered entities flexibility in complying with the notice requirement by giving covered entities the option of using the sample notice or developing their own notice. Although OCR considered requiring covered entities to post the notice in 15 languages (Spanish (or Spanish Creole), Chinese, Vietnamese, Korean, Tagalog, Russian, Arabic, French Creole, French (including Patois, Cajun), Portuguese (or Portuguese Creole), Polish, Japanese, Italian, German, and Persian (Farsi)), we rejected that option. Instead, we are providing the notice translated into 64 languages, and are allowing covered entities the discretion to post one or more of the translated notices. We believe that making translated notices readily available to covered entities maximizes efficiency and economies of scale, provides flexibility while minimizing burden, and helps provide greater access for beneficiaries and consumers. Additionally, although OCR considered requiring covered entities to create their own taglines in the top 15 national languages spoken by individuals with limited English proficiency, we rejected that option. Instead, OCR is making available to covered entities the taglines in 64 languages. As the tagline requirement for the covered entities only requires the cost of printing and posting, this burden is expected to be minimal.

OCR considered not providing training materials to covered entities on the requirements of the regulation. However, in order to reduce costs and burden, OCR is providing these materials, which will reduce covered entities' costs of developing training materials from \$500 per entity to \$125 per entity, resulting in a savings of approximately \$104 million. Entities are assumed to bear one quarter of the total costs. These costs result from paying the presenters who will run the training sessions, providing classroom space, and supplementing the training materials that OCR is making available (should they choose to do so).

OCR considered remaining silent on covered entities' obligations to comply with Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency. We rejected this approach because we were concerned that OCR's silence would create ambiguity about covered entities' obligations to individuals with limited English proficiency and could jeopardize the access of individuals with limited

³⁸⁰ Teresa A. Coughlin, John Holahan, Kyle Caswell, and Megan McGrath, The Henry J. Kaiser Family Foundation, *Uncompensated Care for the Uninsured in 2013: A Detailed Examination* (May 30, 2014), p. 4. <https://kaiserfamilyfoundation.files.wordpress.com/2014/05/8596-uncompensated-care-for-the-uninsured-in-2013.pdf>.

³⁸¹ U.S. Dep't of Health & Human Servs., Office of the Assistant Sec'y for Planning and Eval., Thomas DeLeire, Karen Joynt, and Ruth McDonald, *ASPE Issue Brief, Impact of Insurance Expansion on Hospital Uncompensated Care Costs in 2014* (Sept. 24, 2015) https://aspe.hhs.gov/sites/default/files/pdf/77061/ib_UncompensatedCare.pdf.

English proficiency to covered entities' health programs and activities. Clearly explaining the standards also promotes compliance and reduces enforcement costs. Options for addressing the prohibition of national origin discrimination as it affects individuals with limited English proficiency are discussed in the preamble to the proposed rule.

OCR considered a regulatory scheme requiring covered entities to provide meaningful access to each individual with limited English proficiency by providing effective language assistance services, at no cost, unless such action would result in an undue burden or fundamental alteration. OCR also considered requiring covered entities of a certain type or size to have enhanced obligations to provide language assistance services. Such enhanced obligations would include providing a predetermined range of language assistance services in certain non-English languages that met defined thresholds. A covered entity that was not of a certain type or size still would be required to provide meaningful access to each individual with limited English proficiency in its health programs and activities, but the covered entity would not have to provide a predetermined range of language assistance services in certain non-English languages. OCR also explored applying the threshold requirement to standardized vital documents on a national, State, or county level, as well as specific to a covered entity's geographic service area.

The strengths of these alternate regulatory schemes included limited obligations for small businesses providing health programs or activities and defined standards for larger entities. The costs of these approaches included the complexity of the regulatory scheme and the potential burden on the covered entities of a certain type or size that would have enhanced applications. OCR determined these costs outweigh the benefits.

OCR considered drafting new provisions addressing effective communication (apart from communication through electronic and information technology) with individuals with disabilities, but instead is incorporating provisions of the regulation implementing Title II of the ADA to ensure consistency for covered entities and potentially reduce burden by limiting resources spent on training and modification of policies and procedures.

Options regarding communication through electronic and information technology are discussed in the

preamble to the regulation. Regarding the accessibility requirements under the proposed regulation, OCR at first considered a narrower interpretation that the rule applied only to access to health programs and activities provided through covered entities' Web sites.

However, we chose a broader interpretation, to include both Web sites and other means of electronic and information technology. While this could potentially increase the burden on recipients of Federal financial assistance and State-based Marketplaces, this would offer clarity to covered entities, increase the benefit of the rule, and help enhance access for individuals with disabilities.

In the area of compliance, OCR considered having one set of procedures for all compliance activities involving recipients of Federal financial assistance and State-based MarketplaceSM entities. Instead, OCR decided to adopt the unique Age Act procedures³⁸² for age-related compliance activities under Section 1557 because Age Act compliance activities and Section 1557 compliance activities regarding age discrimination are likely to substantially overlap.

With regard to other areas of compliance, OCR considered developing a separate set of procedures for Section 1557 compliance activities involving HHS health programs and activities, but decided to largely adopt the existing procedures for disability compliance activities involving HHS health programs and activities (with some enhancement) to improve efficiencies for OCR and the HHS health programs and activities covered by Section 1557.

V. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold level is approximately \$146 million.

The Unfunded Mandates Reform Act does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those "Federal mandate" costs resulting from: (1)

³⁸² The Age Act procedures, for example, require mediation of all age discrimination complaints, and exhaustion of administrative remedies prior to the filing of a civil lawsuit. 45 CFR 91.43, 91.50.

Imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

Our impact analysis shows that burden associated with training staff working for covered entities will be spread widely across health care entities, State and local governmental entities, and a substantial number of health insurance issuers. The analysis estimates the unfunded burden will be about \$422 million in training and familiarization costs. We project that for the first few years following promulgation of the final rule, private sector costs for investigating discrimination complaints may amount to \$87 million per year. Within the first five years following the final rule's promulgation, we anticipate complaints will increase, and then eventually drop off as covered entities modify their policies and practices in response to the final rule.

As we explain in the RIA, we believe there will be benefits gained from the promulgation of this regulation in the form of reduction in discrimination based on race, color, national origin, sex, age, and disability, and the corresponding improvement in the quality of care to underserved communities. In response to comments concerning the costs to covered entities, we note that we have not included some changes that would have been beneficial to individuals because we recognize that they would be costly for covered entities.

VI. Executive Order 13132: Federalism

As required by Executive Order 13132³⁸³ on Federalism, OCR examined the effects of provisions in the regulation on the relationship between the Federal government and the States. OCR has concluded that the regulation does have Federalism implications but preempts State law only where the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.

The regulation attempts to balance State autonomy with the necessity of creating a Federal floor that will provide a uniform level of nondiscrimination protection across the country. The regulation restricts regulatory preemption of State law to the minimum level necessary to achieve the objectives of the underlying Federal statute, Section 1557 of the ACA.

³⁸³ Exec. Order No. 13132, 64 FR 43255 (1999).

It is recognized that the States generally have laws that relate to nondiscrimination against individuals on a variety of bases. State laws continue to be enforceable, unless they prevent application of the final rule. The final rule explicitly provides that it is not to be construed to supersede State or local laws that provide additional protections against discrimination on any basis articulated under the regulation. Provisions of State law relating to nondiscrimination that is “more stringent” than the proposed Federal regulatory requirements or implementation specifications will continue to be enforceable.

Section 3(b) of Executive Order 13132 recognizes that national action limiting the policymaking discretion of States will be imposed only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance. Discrimination issues in relation to health care are of national concern by virtue of the scope of interstate health commerce. The ACA’s provisions reflect this position.

Section 3(d)(2) of Executive Order 13132 requires that where possible, the Federal government defer to the States to establish standards. Title I of the ACA authorized the Secretary to promulgate regulations to implement Section 1557, and we have done so accordingly.

Section 4(a) of Executive Order 13132 expressly contemplates preemption when there is a conflict between exercising State and Federal authority under a Federal statute. Section 4(b) of the Executive Order authorizes preemption of State law in the Federal rulemaking context when “the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.” The approach in this regulation is consistent with these standards in the Executive Order in superseding State authority only when such authority is inconsistent with standards established pursuant to the grant of Federal authority under the statute.

Section 6(b) of Executive Order 13132 includes some qualitative discussion of substantial direct compliance costs that State and local governments could incur as a result of a proposed regulation. We have determined that the costs of the final rule will not impose substantial direct compliance costs on State or local governments. We have considered the cost burden that this rule will impose on State and local health care and benefit programs, and estimate State and local government costs will be in the order of \$17.8 million in the first two

years of implementation. The \$17.8 million represents the sum of the costs of training State workers and enforcement costs attributable to State agencies analyzed above.

VII. Regulatory Flexibility Act (RFA)

The RFA requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule will have a significant impact on a substantial number of small entities. The RFA generally defines a “small entity” as:

(1) A proprietary firm meeting the size standards of the Small Business Administration (SBA);

(2) A nonprofit organization that is not dominant in its field; or

(3) A small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of “small entity”).

HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3% for 5% or more of affected small entities.

In instances where OCR judged that the final rule would have a significant impact on a substantial number of small entities, we considered alternatives to reduce the burden. To accomplish our task, we first identified all the small entities that may be impacted, and then evaluated whether the economic burden we determined in the RIA represents a significant economic impact.

A. Entities That Will Be Affected

HHS has traditionally classified most health care providers as small entities even though some nonprofit providers would not meet the definition of “small entity” were they proprietary firms. Nonprofit entities are small if they are independently owned and operated and are not dominant in their fields.

The CMS Provider of Service file has indicators for profit and nonprofit entities, but these have proven to be unreliable. The Census data identifies firms’ tax status by profit and non-profit status but only reports revenues and does not report them by the profit and non-profit status of the entity.

1. Physicians

One class of providers we do not automatically classify as small businesses is physician practices. Physician practices are businesses and therefore are “small” if they meet the SBA’s definition. The current size standard for physicians (excluding mental health specialists) (North American Industry Classification System code 62111) is annual receipts

of less than \$11 million.³⁸⁴ Using the Census data showing the number of firms, employees and payroll, we selected physicians that reported fewer than 20 employees as the top end for small physician offices. This equaled 17,835 entities or 9.6% of all physician offices defined as “large.” This left 167,814 offices or 90.4% as “small.”³⁸⁵

2. Pharmacies

Pharmacies also are businesses, and the size standard for them is annual receipts of less than \$27.5 million. According to Census Statistics of U.S. Businesses, there are 18,852 pharmacy and drug store firms (North American Industry Classification System code 44611). Because of the lack of revenue or receipt data for pharmacies, we are unable to estimate the number of small pharmacies based on the SBA size standard. However, using the number of employees taken from the Statistics of U.S. Businesses as a proxy for revenues, the data is divided by number of employees per firm and shows the number of employers with fewer than 20 employees and those with more than 20 employees.³⁸⁶ The number of firms with fewer than 20 employees is 16,520 and represents 88% of the total number of pharmacy firms. It seemed reasonable to assume that firms with fewer than 20 employees satisfy the SBA size standard and thus we accepted that the number of small pharmacy firms equaled 16,520. As with the number of small physician offices, our method can only identify the minimum number of “small” pharmacies that meet the SBA size standard. We cannot determine the actual number of “small” pharmacies.

3. Health Insurance Issuers

Another class of covered entities that are business enterprises is health insurance issuers. The SBA size standard for health insurance issuers is annual receipts of \$38.5 million. Although the Blue Cross/Blue Shield companies that operate in some markets are organized as nonprofit entities, they often are large enough so as to not meet the definition of “small entity.”

³⁸⁴ U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes. Small Business Administration, (June, 2016), <https://www.sba.gov/sites/default/files/Size5FStandards5FTable.pdf>.

³⁸⁵ Physician practices may earn more than \$11 million per year and that would reduce the number of “large” practices to be excluded from the analysis. But as we will later show, large practices will have proportionally larger workforce staff that must be excluded from the analysis.

³⁸⁶ U.S. Census Bureau, Statistics of U.S. Businesses, *supra* note 314.

Unfortunately, we cannot use the Census revenue data for estimating the number of small health insurance issuers because the Census data combines life and health insurance. Substituting costs for revenues allows us to obtain a rough estimate of the number of large insurance issuers, realizing that cost will probably be less than revenues, thus giving us a lower count of large issuers. Using the National Health Expenditure for 2013, net cost of health insurance equaled

\$173.6 billion. However, the 2012 Census data report a total of 815 health insurance issuers. Dividing the \$174 billion in costs by the number of insurance issuers reported in the census tables yields average costs of over \$213 million, which means that average annual revenues per issuer exceeds \$213 million. We concluded, therefore, that there are almost no small insurance issuers. The above analysis comports with the conclusion CMS published in

the Health Insurance Web Portal Requirements.³⁸⁷

4. Local Government Entities

We also excluded local governmental entities from our count of small entities because we lack the data to classify them by populations of fewer than 50,000. The following table shows the number of small covered entities we estimated could be affected by the proposed rule.

TABLE 6—SMALL COVERED ENTITIES

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
62141	HMO medical centers	104
62142	Kidney dialysis centers	492
62143	Freestanding ambulatory surgical and emergency centers	4,121
621498	All other outpatient care centers	5,399
6215	Medical and diagnostic laboratories	7,958
6216	Home health care services	21,668
6219	All other ambulatory health care services	6,956
62321	Residential mental retardation facilities	6,225
62199	General medical and surgical hospitals	3,067
621991	Psychiatric and substance abuse hospitals	411
6221	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing care facilities (skilled nursing facilities)	8,623
44611	Pharmacies and drug stores	16,520
6211	Offices of physicians	167,814
	Navigator grantees	100
	Total small entities	254,998

B. Whether the Rule Will Have a Significant Economic Impact on Covered Small Entities

Total undiscounted costs associated with the final rule are an average of \$189 million per year over a five year period. If all of those costs are borne by small entities, this amounts to an average of \$739 each year over that five year period. As a result, we believe that fewer than 5% of all small entities will experience a burden of greater than 3% of their revenues. Ambulatory health care services facilities (North American Industry Classification System 621), for example, are small entities with an average of 13 employees and revenue of \$1.7 million based on 2012 reported data for employees of 6.4 million and total revenues of \$825.7 million for

485,235 firms.³⁸⁸ In addition, the majority of the costs associated with this final rule are proportional to the size of entities, meaning that even the smallest of the affected entities are unlikely to face a substantial impact. Thus, we would not consider this regulation a significant burden on a substantial number of small entities, and, therefore, the Secretary certifies that the final rule will not have a significant impact on a substantial number of small entities.

VIII. Conclusion

For the most part, because this regulation is consistent with existing standards applicable to the covered entities, the new burdens created by its issuance are minimal. The major impacts are in the areas of voluntary training, posting of notices, enforcement

(where increased caseloads pose incremental costs on covered entities), voluntary development of language access plans, and revisions or development of new policies and procedures. The final rule does not include broad expansions of existing civil rights requirements on covered entities, and therefore minimizes the imposition of new burdens. Nevertheless, it is still a major rule with economically significant costs. The annualized cost of this rule over the first five years following its publication is \$192.5 million using a discount rate of 3%, and \$197.8 million using a discount rate of 7%. This RIA was organized and designed to explain the origin of these cost impacts and to incorporate relevant public comments.

³⁸⁷ 75 CFR 24481, May 5, 2010.

³⁸⁸ U.S. Dep't of Labor, Bureau of Labor Statistics, Industries at a Glance, <http://www.bls.gov/iag/tgs/iag621.htm> (last visited Mar. 26, 2016).

TABLE 7—ACCOUNTING STATEMENT

Accounting statement				
Category	Primary estimate	Low estimate	High estimate	Source
BENEFITS				
Qualitative Benefits (02)	• Potential health improvements and longevity extensions as a result of reduced barriers to medical care for transgender individuals.		RIA
COSTS (millions)				
Annualized monetized	Covered entities train 40% of their employees on the new regulations	Covered entities train 60% of their employees on the new regulations	RIA RIA
3%	192.5	177.0	208.1	
7%	197.8	181.4	214.2	
Non-quantified costs (02)	Costs of increased provision of health care services as a result of reduced barriers to access for transgender individuals.		RIA
Transfers (02)	Health insurance premium reductions for affected women, with offsetting increases for other premium payers in affected plans.		RIA
Effects on State and Local Governments (02)	\$17.8 million costs in the first 2 years (training + enforcement)		RIA
Effects on Small Entities (02)	Average of less than \$1,000 per small entity per year		RFA

List of Subjects in 45 CFR Part 92

Administrative practice and procedure, Civil rights, Discrimination, Elderly, Health care, Health facilities, Health insurance, Health programs and activities, Individuals with disabilities, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

For the reasons set forth in the preamble, the Department of Health and Human Services adds 45 CFR part 92 as follows:

PART 92—NONDISCRIMINATION ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AGE, OR DISABILITY IN HEALTH PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE AND HEALTH PROGRAMS OR ACTIVITIES ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OR ENTITIES ESTABLISHED UNDER TITLE I OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

Subpart A—General Provisions

- 92.1 Purpose and effective date.
- 92.2 Application.
- 92.3 Relationship to other laws.
- 92.4 Definitions.
- 92.5 Assurances required.
- 92.6 Remedial action and voluntary action.
- 92.7 Designation of responsible employee and adoption of grievance procedures.
- 92.8 Notice requirement.

Subpart B—Nondiscrimination Provisions

- 92.101 Discrimination prohibited.

Subpart C—Specific Applications to Health Programs and Activities

- 92.201 Meaningful access for individuals with limited English proficiency.
- 92.202 Effective communication for individuals with disabilities.
- 92.203 Accessibility standards for buildings and facilities.
- 92.204 Accessibility of electronic and information technology.
- 92.205 Requirement to make reasonable modifications.
- 92.206 Equal program access on the basis of sex.
- 92.207 Nondiscrimination in health-related insurance and other health-related coverage.
- 92.208 Employer liability for discrimination in employee health benefit programs.
- 92.209 Nondiscrimination on the basis of association.

Subpart D—Procedures

- 92.301 Enforcement mechanisms.
- 92.302 Procedures for health programs and activities conducted by recipients and State-based Marketplaces.
- 92.303 Procedures for health programs and activities administered by the Department.

Appendix A to Part 92—Sample Notice Informing Individuals About Nondiscrimination and Accessibility

Requirements and Sample
Nondiscrimination Statement
Appendix B to Part 92—Sample Tagline
Informing Individuals With Limited
English Proficiency of Language
Assistance Services
Appendix C to Part 92—Sample Section 1557
of the Affordable Care Act Grievance
Procedure

Authority: 42 U.S.C. 18116, 5 U.S.C. 301.

Subpart A—General Provisions

§ 92.1 Purpose and effective date.

The purpose of this part is to implement Section 1557 of the Patient Protection and Affordable Care Act (ACA) (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Section 1557 provides that, except as provided in Title I of the ACA, an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or Section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the ACA. This part applies to health programs or activities administered by recipients of Federal financial assistance from the Department, Title I entities that administer health programs or activities, and Department-administered health programs or activities. The effective date of this part shall be July 18, 2016, except to the extent that provisions of this part require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

§ 92.2 Application.

(a) Except as provided otherwise in this part, this part applies to every health program or activity, any part of which receives Federal financial assistance provided or made available by the Department; every health program or activity administered by the Department; and every health program

or activity administered by a Title I entity.

(b)(1) Exclusions to the application of the Age Discrimination Act of 1975, as set forth at 45 CFR 91.3(b)(1), apply to claims of discrimination based on age under Section 1557 or this part.

(2) Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required.

(c) Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 92.3 Relationship to other laws.

(a) *Rule of interpretation.* Neither Section 1557 nor this part shall be construed to apply a lesser standard for the protection of individuals from discrimination than the standards applied under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, or the regulations issued pursuant to those laws.

(b) *Other laws.* Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals under Title VI of the Civil Rights Act of 1964, Title VII of the Civil Rights Act of 1964, the Architectural Barriers Act of 1968, Title IX of the Education Amendments of 1972, Sections 504 or 508 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, the Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008, or other Federal laws or to supersede State or local laws that provide additional protections against discrimination on any basis described in § 92.1.

§ 92.4 Definitions.

As used in this part, the term—
1991 Standards means the 1991 ADA Standards for Accessible Design, published at Appendix A to 28 CFR part 36 on July 26, 1991, and republished as Appendix D to 28 CFR part 36 on September 15, 2010.

2010 Standards means the 2010 ADA Standards for Accessible Design, as defined at 28 CFR 35.104.

ACA means the Patient Protection and Affordable Care Act (Pub. L. 111–148, 124 Stat. 119 (2010) as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111–152, 124 Stat. 1029 (codified in scattered sections of U.S.C.)).

ADA means the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*), as amended.

Age means how old an individual is, or the number of elapsed years from the date of an individual's birth.

Age Act means the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), as amended.

Applicant means an individual who applies to participate in a health program or activity.

Auxiliary aids and services include:

(1) Qualified interpreters on-site or through video remote interpreting (VRI) services, as defined in 28 CFR 35.104 and 36.303(b); note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunication products and systems, text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology; or other effective methods of making aurally delivered information available to individuals who are deaf or hard of hearing;

(2) Qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs; large print materials; accessible electronic and information technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision;

(3) Acquisition or modification of equipment and devices; and

(4) Other similar services and actions.

Covered entity means:

(1) An entity that operates a health program or activity, any part of which receives Federal financial assistance;

(2) An entity established under Title I of the ACA that administers a health program or activity; and

(3) The Department.

Department means the U.S. Department of Health and Human Services.

Director means the Director of the Office for Civil Rights (OCR) of the Department.

Disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment, as defined and construed in the Rehabilitation Act, 29 U.S.C. 705(9)(B), which incorporates the definition of disability in the ADA, 42 U.S.C. 12102, as amended. Where this part cross-references regulatory provisions that use the term “handicap,” “handicap” means “disability” as defined in this section.

Electronic and information technology means the same as “electronic and information technology,” or any term that replaces “electronic and information technology,” as it is defined in 36 CFR 1194.4.

Employee health benefit program means:

(1) Health benefits coverage or health insurance coverage provided to employees and/or their dependents established, operated, sponsored or administered by, for, or on behalf of one or more employers, whether provided or administered by entities including but not limited to an employer, group health plan (as defined in the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1191b(a)(1)), third party administrator, or health insurance issuer.

(2) An employer-provided or employer-sponsored wellness program;

(3) An employer-provided health clinic; or

(4) Long term care coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer for the benefit of an employer’s employees.

Federal financial assistance. (1) Federal financial assistance means any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other arrangement by which the Federal government provides or otherwise makes available assistance in the form of:

(i) Funds;

(ii) Services of Federal personnel; or

(iii) Real and personal property or any interest in or use of such property, including:

(A) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(B) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal government.

(2) Federal financial assistance the Department provides or otherwise makes available includes Federal financial assistance that the Department plays a role in providing or administering, including all tax credits under Title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to any entity providing health-related insurance coverage for payment to or on behalf of an individual obtaining health-related insurance coverage from that entity or extended by the Department directly to such individual for payment to any entity providing health-related insurance coverage.

Federally-facilitated MarketplaceSM means the same as “Federally-facilitated Exchange” defined in 45 CFR 155.20.

Gender identity means an individual’s internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual’s sex assigned at birth. The way an individual expresses gender identity is frequently called “gender expression,” and may or may not conform to social stereotypes associated with a particular gender. A transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.

Health Insurance MarketplaceSM means the same as “Exchange” defined in 45 CFR 155.20.

Health program or activity means the provision or administration of health-related services, health-related insurance coverage, or other health-related coverage, and the provision of assistance to individuals in obtaining health-related services or health-related insurance coverage. For an entity principally engaged in providing or administering health services or health insurance coverage or other health coverage, all of its operations are considered part of the health program or activity, except as specifically set forth otherwise in this part. Such entities include a hospital, health clinic, group health plan, health insurance issuer, physician’s practice, community health center, nursing facility, residential or community-based treatment facility, or other similar entity. A health program or activity also includes all of the operations of a State Medicaid program, a Children’s Health Insurance Program, and the Basic Health Program.

HHS means the U.S. Department of Health and Human Services.

Individual with a disability means any individual who has a disability as defined for the purpose of Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 705(20)(B)–(F), as amended.

Where this part cross-references regulatory provisions applicable to a “handicapped individual,”

“handicapped individual” means “individual with a disability” as defined in this section.

Individual with limited English proficiency means an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English.

Language assistance services may include, but are not limited to:

(1) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency;

(2) Written translation, performed by a qualified translator, of written content in paper or electronic form into languages other than English; and

(3) Taglines.

National origin includes, but is not limited to, an individual’s, or his or her ancestor’s, place of origin (such as country or world region) or an individual’s manifestation of the physical, cultural, or linguistic characteristics of a national origin group.

On the basis of sex includes, but is not limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity.

Qualified bilingual/multilingual staff means a member of a covered entity’s workforce who is designated by the covered entity to provide oral language assistance as part of the individual’s current, assigned job responsibilities and who has demonstrated to the covered entity that he or she:

(1) Is proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology; and

(2) Is able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.

Qualified individual with a disability means, with respect to a health program or activity, an individual with a disability who, with or without reasonable modifications to policies, practices, or procedures, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of aids, benefits, or services offered or provided by the health program or activity.

Qualified interpreter for an individual with a disability. (1) A qualified interpreter for an individual with a disability means an interpreter who via a remote interpreting service or an on-site appearance:

(i) Adheres to generally accepted interpreter ethics principles, including client confidentiality; and

(ii) is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary, terminology and phraseology.

(2) For an individual with a disability, qualified interpreters can include, for example, sign language interpreters, oral transliterators (individuals who represent or spell in the characters of another alphabet), and cued language transliterators (individuals who represent or spell by using a small number of handshapes).

Qualified interpreter for an individual with limited English proficiency means an interpreter who via a remote interpreting service or an on-site appearance:

(1) Adheres to generally accepted interpreter ethics principles, including client confidentiality;

(2) has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language; and

(3) is able to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

Qualified translator means a translator who:

(1) Adheres to generally accepted translator ethics principles, including client confidentiality;

(2) has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language; and

(3) is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

Recipient means any State or its political subdivision, or any instrumentality of a State or its political subdivision, any public or private agency, institution, or organization, or other entity, or any individual, to whom Federal financial assistance is extended directly or through another recipient and which operates a health program or activity, including any subunit, successor, assignee, or transferee of a recipient.

Section 504 means Section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112; 29 U.S.C. 794), as amended.

Section 1557 means Section 1557 of the ACA (42 U.S.C. 18116).

Sex stereotypes means stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. These stereotypes can include the expectation that individuals will consistently identify with only one gender and that they will act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes also include gendered expectations related to the appropriate roles of a certain sex.

State-based MarketplaceSM means a Health Insurance MarketplaceSM established by a State pursuant to 45 CFR 155.100 and approved by the Department pursuant to 45 CFR 155.105.

Taglines mean short statements written in non-English languages that indicate the availability of language assistance services free of charge.

Title I entity means any entity established under Title I of the ACA, including State-based Marketplaces and Federally-facilitated Marketplaces.

Title VI means Title VI of the Civil Rights Act of 1964 (Pub. L. 88–352; 42 U.S.C. 2000d *et seq.*), as amended.

Title IX means Title IX of the Education Amendments of 1972 (Pub. L. 92–318; 20 U.S.C. 1681 *et seq.*), as amended.

§ 92.5 Assurances required.

(a) *Assurances.* An entity applying for Federal financial assistance to which this part applies shall, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director, that the entity's health programs and activities will be operated in compliance with Section 1557 and this part. A health insurance issuer seeking certification to participate in a Health Insurance MarketplaceSM or a State seeking approval to operate a State-based

MarketplaceSM to which Section 1557 or this part applies shall, as a condition of certification or approval, submit an assurance, on a form specified by the Director, that the health program or activity will be operated in compliance with Section 1557 and this part. An applicant or entity may incorporate this assurance by reference in subsequent applications to the Department for Federal financial assistance or requests for certification to participate in a Health Insurance MarketplaceSM or approval to operate a State-based MarketplaceSM.

(b) *Duration of obligation.* The duration of the assurances required by this subpart is the same as the duration of the assurances required in the Department's regulations implementing Section 504, 45 CFR 84.5(b).

(c) *Covenants.* When Federal financial assistance is provided in the form of real property or interest, the same conditions apply as those contained in the Department's regulations implementing Section 504, at 45 CFR 84.5(c), except that the nondiscrimination obligation applies to discrimination on all bases covered under Section 1557 and this part.

§ 92.6 Remedial action and voluntary action.

(a) *Remedial action.* (1) If the Director finds that a recipient or State-based MarketplaceSM has discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of Section 1557 or this part, such recipient or State-based MarketplaceSM shall take such remedial action as the Director may require to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of Section 1557 or this part, and where another recipient exercises control over the recipient that has discriminated, the Director, where appropriate, may require either or both entities to take remedial action.

(3) The Director may, where necessary to overcome the effects of discrimination in violation of Section 1557 or this part, require a recipient or State-based MarketplaceSM to take remedial action with respect to:

(i) Individuals who are no longer participants in the recipient's or State-based MarketplaceSM's health program or activity but who were participants in the health program or activity when such discrimination occurred; or

(ii) Individuals who would have been participants in the health program or

activity had the discrimination not occurred.

(b) *Voluntary action.* A covered entity may take steps, in addition to any action that is required by Section 1557 or this part, to overcome the effects of conditions that result or resulted in limited participation in the covered entity's health programs or activities by individuals on the basis of race, color, national origin, sex, age, or disability.

§ 92.7 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* Each covered entity that employs 15 or more persons shall designate at least one employee to coordinate its efforts to comply with and carry out its responsibilities under Section 1557 and this part, including the investigation of any grievance communicated to it alleging noncompliance with Section 1557 or this part or alleging any action that would be prohibited by Section 1557 or this part. For the Department, including the Federally-facilitated Marketplaces, the Director will be deemed the responsible employee under this section.

(b) *Adoption of grievance procedures.* Each covered entity that employs 15 or more persons shall adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557 or this part. For the Department, including the Federally-facilitated Marketplaces, the procedures for addressing complaints of discrimination on the grounds covered under Section 1557 or this part will be deemed grievance procedures under this section.

§ 92.8 Notice requirement.

(a) Each covered entity shall take appropriate initial and continuing steps to notify beneficiaries, enrollees, applicants, and members of the public of the following:

(1) The covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities;

(2) The covered entity provides appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, free of charge and in a timely manner, when such aids and services are necessary to ensure an equal opportunity to participate to individuals with disabilities;

(3) The covered entity provides language assistance services, including translated documents and oral interpretation, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited English proficiency;

(4) How to obtain the aids and services in paragraphs (a)(2) and (3) of this section;

(5) An identification of, and contact information for, the responsible employee designated pursuant to § 92.7(a), if applicable;

(6) The availability of the grievance procedure and how to file a grievance, pursuant to § 92.7(b), if applicable; and

(7) How to file a discrimination complaint with OCR in the Department.

(b) Within 90 days of the effective date of this part, each covered entity shall:

(1) As described in paragraph (f)(1) of this section, post a notice that conveys the information in paragraphs (a)(1) through (7) of this section; and

(2) As described in paragraph (g)(1) of this section, if applicable, post a nondiscrimination statement that conveys the information in paragraph (a)(1) of this section.

(c) For use by covered entities, the Director shall make available, electronically and in any other manner that the Director determines appropriate, the content of a sample notice that conveys the information in paragraphs (a)(1) through (7) of this section, and the content of a sample nondiscrimination statement that conveys the information in paragraph (a)(1) of this section, in English and in the languages triggered by the obligation in paragraph (d)(1) of this section.

(d) Within 90 days of the effective date of this part, each covered entity shall:

(1) As described in paragraph (f)(1) of this section, post taglines in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States; and

(2) As described in paragraph (g)(2) of this section, if applicable, post taglines in at least the top two languages spoken by individuals with limited English proficiency of the relevant State or States.

(e) For use by covered entities, the Director shall make available, electronically and in any other manner that the Director determines appropriate, taglines in the languages triggered by the obligation in paragraph (d)(1) of this section.

(f)(1) Each covered entity shall post the notice required by paragraph (a) of this section and the taglines required by

paragraph (d)(1) of this section in a conspicuously-visible font size:

(i) In significant publications and significant communications targeted to beneficiaries, enrollees, applicants, and members of the public, except for significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures;

(ii) In conspicuous physical locations where the entity interacts with the public; and

(iii) In a conspicuous location on the covered entity's Web site accessible from the home page of the covered entity's Web site.

(2) A covered entity may also post the notice and taglines in additional publications and communications.

(g) Each covered entity shall post, in a conspicuously-visible font size, in significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures:

(1) The nondiscrimination statement required by paragraph (b)(2) of this section; and

(2) The taglines required by paragraph (d)(2) of this section.

(h) A covered entity may combine the content of the notice required in paragraph (a) of this section with the content of other notices if the combined notice clearly informs individuals of their civil rights under Section 1557 and this part.

Subpart B—Nondiscrimination Provisions

§ 92.101 Discrimination prohibited.

(a) *General.* (1) Except as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies.

(2) This part does not apply to employment, except as provided in § 92.208.

(b) *Specific discriminatory actions prohibited.* Under any health program or activity to which this part applies:

(1)(i) Each covered entity must comply with the regulation implementing Title VI, at § 80.3(b)(1) through (6) of this subchapter.

(ii) No covered entity shall, on the basis of race, color, or national origin, aid or perpetuate discrimination against any person by providing significant assistance to any entity or person that discriminates on the basis of race, color, or national origin in providing any aid, benefit, or service to beneficiaries of the covered entity's health program or activity.

(2)(i) Each recipient and State-based MarketplaceSM must comply with the regulation implementing Section 504, at §§ 84.4(b), 84.21 through 84.23(b), 84.31, 84.34, 84.37, 84.38, and 84.41 through 84.52(c) and 84.53 through 84.55 of this subchapter. Where this paragraph cross-references regulatory provisions that use the term “recipient,” the term “recipient or State-based MarketplaceSM” shall apply in its place.

(ii) The Department, including the Federally-facilitated Marketplaces, must comply with the regulation implementing Section 504, at §§ 85.21(b), 85.41 through 85.42, and 85.44 through 85.51 of this subchapter.

(3)(i) Each covered entity must comply with the regulation implementing Title IX, at § 86.31(b)(1) through (8) of this subchapter. Where this paragraph cross-references regulatory provisions that use the term “student,” “employee,” or “applicant,” these terms shall be replaced with “individual.”

(ii) A covered entity may not, directly or through contractual or other arrangements, utilize criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program with respect to individuals on the basis of sex.

(iii) In determining the site or location of a facility, a covered entity may not make selections that have the effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any programs to which this regulation applies, on the basis of sex; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity on the basis of sex.

(iv) A covered entity may operate a sex-specific health program or activity (a health program or activity that is restricted to members of one sex) only if the covered entity can demonstrate an exceedingly persuasive justification, that is, that the sex-specific health program or activity is substantially related to the achievement of an important health-related or scientific objective.

(4)(i) Each covered entity must comply with the regulation implementing the Age Act, at § 91.11(b) of this subchapter.

(ii) No covered entity shall, on the basis of age, aid or perpetuate discrimination against any person by providing significant assistance to any agency, organization, or person that discriminates on the basis of age in

providing any aid, benefit, or service to beneficiaries of the covered entity’s health program or activity.

(5) The enumeration of specific forms of discrimination in this paragraph does not limit the generality of the prohibition in paragraph (a) of this section.

(c) The exceptions applicable to Title VI apply to discrimination on the basis of race, color, or national origin under this part. The exceptions applicable to Section 504 apply to discrimination on the basis of disability under this part. The exceptions applicable to the Age Act apply to discrimination on the basis of age under this part. These provisions are found at §§ 80.3(d), 84.4(c), 85.21(c), 91.12, 91.15, and 91.17–.18 of this subchapter.

(d) Where the regulatory provisions referenced in paragraphs (b)(1), (b)(3), and (b)(4), and paragraph (c) of this section use the term “recipient,” the term “covered entity” shall apply in its place. Where the regulatory provisions referenced in paragraphs (b)(1), (b)(3), and (b)(4) and paragraph (c) of this section use the terms “program or activity” or “program” or “education program,” the term “health program or activity” shall apply in their place.

Subpart C—Specific Applications to Health Programs and Activities

§ 92.201 Meaningful access for individuals with limited English proficiency.

(a) *General requirement.* A covered entity shall take reasonable steps to provide meaningful access to each individual with limited English proficiency eligible to be served or likely to be encountered in its health programs and activities.

(b) *Evaluation of compliance.* In evaluating whether a covered entity has met its obligation under paragraph (a) of this section, the Director shall:

(1) Evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, to the individual with limited English proficiency; and

(2) Take into account other relevant factors, including whether a covered entity has developed and implemented an effective written language access plan, that is appropriate to its particular circumstances, to be prepared to meet its obligations in § 92.201(a).

(c) *Language assistance services requirements.* Language assistance services required under paragraph (a) of this section must be provided free of charge, be accurate and timely, and protect the privacy and independence of

the individual with limited English proficiency.

(d) *Specific requirements for interpreter and translation services.* Subject to paragraph (a) of this section:

(1) A covered entity shall offer a qualified interpreter to an individual with limited English proficiency when oral interpretation is a reasonable step to provide meaningful access for that individual with limited English proficiency; and

(2) A covered entity shall use a qualified translator when translating written content in paper or electronic form.

(e) *Restricted use of certain persons to interpret or facilitate communication.* A covered entity shall not:

(1) Require an individual with limited English proficiency to provide his or her own interpreter;

(2) Rely on an adult accompanying an individual with limited English proficiency to interpret or facilitate communication, except:

(i) In an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available; or

(ii) Where the individual with limited English proficiency specifically requests that the accompanying adult interpret or facilitate communication, the

accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances;

(3) Rely on a minor child to interpret or facilitate communication, except in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available; or

(4) Rely on staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency.

(f) *Video remote interpreting services.*

A covered entity that provides a qualified interpreter for an individual with limited English proficiency through video remote interpreting services in the covered entity’s health programs and activities shall provide:

(1) Real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;

(2) A sharply delineated image that is large enough to display the interpreter’s

face and the participating individual's face regardless of the individual's body position;

(3) A clear, audible transmission of voices; and

(4) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the video remote interpreting.

(g) *Acceptance of language assistance services is not required.* Nothing in this section shall be construed to require an individual with limited English proficiency to accept language assistance services.

§ 92.202 Effective communication for individuals with disabilities.

(a) A covered entity shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in health programs and activities, in accordance with the standards found at 28 CFR 35.160 through 35.164. Where the regulatory provisions referenced in this section use the term "public entity," the term "covered entity" shall apply in its place.

(b) A recipient or State-based MarketplaceSM shall provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

§ 92.203 Accessibility standards for buildings and facilities.

(a) Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based MarketplaceSM shall comply with the 2010 Standards as defined in § 92.4, if the construction or alteration was commenced on or after July 18, 2016, except that if a facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based MarketplaceSM, was not covered by the 2010 Standards prior to July 18, 2016, such facility or part of a facility shall comply with the 2010 Standards, as defined in § 92.4, if the construction was commenced after January 18, 2018. Departures from particular technical and scoping requirements by the use of other methods are permitted where substantially equivalent or greater access to and usability of the facility is provided. All newly constructed or altered buildings or facilities subject to

this section shall comply with the requirements for a "public building or facility" as defined in Section 106.5 of the 2010 Standards.

(b) Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based MarketplaceSM in conformance with the 1991 Standards or the 2010 Standards as defined in § 92.4 shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction or alteration was commenced on or before July 18, 2016. Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based MarketplaceSM in conformance with the Uniform Federal Accessibility Standards as defined in § 92.4, shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction was commenced before July 18, 2016 and such facility was not covered by the 1991 Standards or 2010 Standards.

§ 92.204 Accessibility of electronic and information technology.

(a) Covered entities shall ensure that their health programs or activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities. When undue financial and administrative burdens or a fundamental alteration exist, the covered entity shall provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

(b) Recipients and State-based Marketplaces shall ensure that their health programs and activities provided through Web sites comply with the requirements of Title II of the ADA.

§ 92.205 Requirement to make reasonable modifications.

A covered entity shall make reasonable modifications to policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term "reasonable modifications" shall be interpreted in a manner consistent with the term as set forth in the ADA Title II regulation at 28 CFR 35.130(b)(7).

§ 92.206 Equal program access on the basis of sex.

A covered entity shall provide individuals equal access to its health programs or activities without discrimination on the basis of sex; and a covered entity shall treat individuals consistent with their gender identity, except that a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available.

§ 92.207 Nondiscrimination in health-related insurance and other health-related coverage.

(a) *General.* A covered entity shall not, in providing or administering health-related insurance or other health-related coverage, discriminate on the basis of race, color, national origin, sex, age, or disability.

(b) *Discriminatory actions prohibited.* A covered entity shall not, in providing or administering health-related insurance or other health-related coverage:

(1) Deny, cancel, limit, or refuse to issue or renew a health-related insurance plan or policy or other health-related coverage, or deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, or disability;

(2) Have or implement marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability in a health-related insurance plan or policy, or other health-related coverage;

(3) Deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other

limitations or restrictions on coverage, for any health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that an individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available;

(4) Have or implement a categorical coverage exclusion or limitation for all health services related to gender transition; or

(5) Otherwise deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual.

(c) The enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a) of this section.

(d) Nothing in this section is intended to determine, or restrict a covered entity from determining, whether a particular health service is medically necessary or otherwise meets applicable coverage requirements in any individual case.

§ 92.208 Employer liability for discrimination in employee health benefit programs.

A covered entity that provides an employee health benefit program to its employees and/or their dependents shall be liable for violations of this part in that employee health benefit program only when:

(a) The entity is principally engaged in providing or administering health services, health insurance coverage, or other health coverage;

(b) The entity receives Federal financial assistance a primary objective of which is to fund the entity's employee health benefit program; or

(c) The entity is not principally engaged in providing or administering health services, health insurance coverage, or other health coverage, but operates a health program or activity, which is not an employee health benefit program, that receives Federal financial assistance; except that the entity is liable under this part with regard to the provision or administration of employee health benefits only with respect to the employees in that health program or activity.

§ 92.209 Nondiscrimination on the basis of association.

A covered entity shall not exclude from participation in, deny the benefits

of, or otherwise discriminate against an individual or entity in its health programs or activities on the basis of the race, color, national origin, sex, age, or disability of an individual with whom the individual or entity is known or believed to have a relationship or association.

Subpart D—Procedures

§ 92.301 Enforcement mechanisms.

(a) The enforcement mechanisms available for and provided under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, or the Age Discrimination Act of 1975 shall apply for purposes of Section 1557 as implemented by this part.

(b) Compensatory damages for violations of Section 1557 are available in appropriate administrative and judicial actions brought under this rule.

§ 92.302 Procedures for health programs and activities conducted by recipients and State-based Marketplaces.

(a) The procedural provisions applicable to Title VI apply with respect to administrative enforcement actions concerning discrimination on the basis of race, color, national origin, sex, and disability discrimination under Section 1557 or this part. These procedures are found at §§ 80.6 through 80.11 of this subchapter and part 81 of this subchapter.

(b) The procedural provisions applicable to the Age Act apply with respect to enforcement actions concerning age discrimination under Section 1557 or this part. These procedures are found at §§ 91.41 through 91.50 of this subchapter.

(c) When a recipient fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may find noncompliance with Section 1557 and initiate appropriate enforcement procedures, including beginning the process for fund suspension or termination and taking other action authorized by law.

(d) An individual or entity may bring a civil action to challenge a violation of Section 1557 or this part in a United States District Court in which the recipient or State-based MarketplaceSM is found or transacts business.

§ 92.303 Procedures for health programs and activities administered by the Department.

(a) This section applies to discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities administered by the

Department, including the Federally-facilitated Marketplaces.

(b) The procedural provisions applicable to Section 504 at §§ 85.61 through 85.62 of this subchapter shall apply with respect to enforcement actions against the Department concerning discrimination on the basis of race, color, national origin, sex, age, or disability under Section 1557 or this part. Where this section cross-references regulatory provisions that use the term "handicap," the term "race, color, national origin, sex, age, or disability" shall apply in its place.

(c) The Department shall permit access by OCR to its books, records, accounts, other sources of information, and facilities as may be pertinent to ascertain compliance with Section 1557 or this part. Where any information required of the Department is in the exclusive possession of any other agency, institution or individual, and the other agency, institution or individual shall fail or refuse to furnish this information, the Department shall so certify and shall set forth what efforts it has made to obtain the information. Asserted considerations of privacy or confidentiality may not operate to bar OCR from evaluating or seeking to enforce compliance with Section 1557 or this part. Information of a confidential nature obtained in connection with compliance evaluation or enforcement shall not be disclosed except where necessary under the law.

(d) The Department shall not intimidate, threaten, coerce, or discriminate against any individual for the purpose of interfering with any right or privilege secured by Section 1557 or this part, or because such individual has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding or hearing under Section 1557 or this part. The identity of complainants shall be kept confidential by OCR, except to the extent necessary to carry out the purposes of Section 1557 or this part.

Appendix A to Part 92—Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements and Sample Nondiscrimination Statement: Discrimination is Against the Law

[Name of covered entity] complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. [Name of covered entity] does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

[Name of covered entity]:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages
- If you need these services, contact [Name of Civil Rights Coordinator]

If you believe that [Name of covered entity] has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: [Name and Title of Civil Rights Coordinator], [Mailing Address], [Telephone number], [TTY number—if covered entity has one], [Fax], [Email]. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, [Name and Title of Civil Rights Coordinator] is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-868-1019, 800-537-7697 (TDD).

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Nondiscrimination statement for significant publications and signification communications that are small-size:

[Name of covered entity] complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

Appendix B to Part 92—Sample Tagline Informing Individuals With Limited English Proficiency of Language Assistance Services

ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1-xxx-xxx-xxxx (TTY: 1-xxx-xxx-xxxx).

Appendix C to Part 92—Sample Section 1557 of the Affordable Care Act Grievance Procedure

It is the policy of [Name of Covered Entity] not to discriminate on the basis of race, color,

national origin, sex, age or disability. [Name of Covered Entity] has adopted an internal grievance procedure providing for prompt and equitable resolution of complaints alleging any action prohibited by Section 1557 of the Affordable Care Act (42 U.S.C. 18116) and its implementing regulations at 45 CFR part 92, issued by the U.S. Department of Health and Human Services. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities. Section 1557 and its implementing regulations may be examined in the office of [Name and Title of Section 1557 Coordinator], [Mailing Address], [Telephone number], [TTY number—if covered entity has one], [Fax], [Email], who has been designated to coordinate the efforts of [Name of Covered Entity] to comply with Section 1557.

Any person who believes someone has been subjected to discrimination on the basis of race, color, national origin, sex, age or disability may file a grievance under this procedure. It is against the law for [Name of Covered Entity] to retaliate against anyone who opposes discrimination, files a grievance, or participates in the investigation of a grievance.

Procedure:

- Grievances must be submitted to the Section 1557 Coordinator within (60 days) of the date the person filing the grievance becomes aware of the alleged discriminatory action.

- A complaint must be in writing, containing the name and address of the person filing it. The complaint must state the problem or action alleged to be discriminatory and the remedy or relief sought.

- The Section 1557 Coordinator (or her/his designee) shall conduct an investigation of the complaint. This investigation may be informal, but it will be thorough, affording all interested persons an opportunity to submit evidence relevant to the complaint. The Section 1557 Coordinator will maintain the files and records of [Name of Covered Entity] relating to such grievances. To the extent possible, and in accordance with applicable law, the Section 1557 Coordinator will take appropriate steps to preserve the confidentiality of files and records relating to grievances and will share them only with those who have a need to know.

- The Section 1557 Coordinator will issue a written decision on the grievance, based on

a preponderance of the evidence, no later than 30 days after its filing, including a notice to the complainant of their right to pursue further administrative or legal remedies.

- The person filing the grievance may appeal the decision of the Section 1557 Coordinator by writing to the (Administrator/Chief Executive Officer/Board of Directors/etc.) within 15 days of receiving the Section 1557 Coordinator's decision. The (Administrator/Chief Executive Officer/Board of Directors/etc.) shall issue a written decision in response to the appeal no later than 30 days after its filing.

The availability and use of this grievance procedure does not prevent a person from pursuing other legal or administrative remedies, including filing a complaint of discrimination on the basis of race, color, national origin, sex, age or disability in court or with the U.S. Department of Health and Human Services, Office for Civil Rights. A person can file a complaint of discrimination electronically through the Office for Civil Rights Complaint Portal, which is available at: <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201.

Complaint forms are available at: <http://www.hhs.gov/ocr/office/file/index.html>. Such complaints must be filed within 180 days of the date of the alleged discrimination.

[Name of covered entity] will make appropriate arrangements to ensure that individuals with disabilities and individuals with limited English proficiency are provided auxiliary aids and services or language assistance services, respectively, if needed to participate in this grievance process. Such arrangements may include, but are not limited to, providing qualified interpreters, providing taped cassettes of material for individuals with low vision, or assuring a barrier-free location for the proceedings. The Section 1557 Coordinator will be responsible for such arrangements.

Dated: May 11, 2016.

Sylvia M. Burwell,
Secretary.

[FR Doc. 2016-11458 Filed 5-13-16; 11:15 am]

BILLING CODE 4153-01-P

EXHIBIT 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 438, 440, and 460

Office of the Secretary

45 CFR Parts 86, 92, 147, 155, and 156

RIN 0945-AA11

Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority

AGENCY: Centers for Medicare & Medicaid Services (CMS); Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (“the Department” or “HHS”) is committed to ensuring the civil rights of all individuals who access or seek to access health programs or activities of covered entities under Section 1557 of the Patient Protection and Affordable Care Act (“ACA”). After considering public comments, in this final rule, the Department revises its Section 1557 regulations, Title IX regulations, and specific regulations of the Centers for Medicare & Medicaid Services (“CMS”) as proposed, with minor and primarily technical corrections. This will better comply with the mandates of Congress, address legal concerns, relieve billions of dollars in undue regulatory burdens, further substantive compliance, reduce confusion, and clarify the scope of Section 1557 in keeping with pre-existing civil rights statutes and regulations prohibiting discrimination on the basis of race, color, national origin, sex, age, and disability.

DATES: This rule is effective August 18, 2020.

FOR FURTHER INFORMATION CONTACT: Luben Montoya, Supervisory Civil Rights Analyst, HHS Office for Civil Rights, at (800) 368-1019 or (800) 537-7697 (TDD).

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I. Executive Summary

A. Purpose

This regulation finalizes the Department's proposed rule concerning Nondiscrimination in Health and Health Education Programs or Activities issued in the **Federal Register** on June 14, 2019 (84 FR 27846), with minor and primarily technical corrections. It makes changes to the Department's existing regulation¹ ("2016 Rule") implementing

Section 1557 of the ACA, 42 U.S.C. 18116. It makes a related amendment to the Department's regulations implementing Title IX of the Education Amendments of 1972 ("Title IX"), and it makes conforming amendments to nondiscrimination provisions within various CMS regulations.

Through Section 1557 of the ACA, Congress applied certain long-standing civil rights nondiscrimination requirements to any health programs or activities that receive Federal financial assistance, and any programs or activities administered by an Executive agency under Title I of the ACA or by an entity established under such Title. It did so by cross-referencing statutes that specify prohibited grounds of discrimination, namely, race, color, national origin, sex, age, or disability, in an array of Federally funded and administered programs or activities. To ensure compliance, Congress dictated that "[t]he enforcement mechanisms provided for and available under" such laws "shall apply for purposes of violations of" Section 1557.²

This final rule returns to the enforcement mechanisms provided for, and available under, those longstanding statutes and the Department's implementing regulations. It eliminates many of the provisions of the 2016 Rule in order to better comply with the mandates of Congress, relieves approximately \$2.9 billion in undue regulatory burdens (over five years), furthers substantive compliance, reduces confusion, and clarifies the scope of Section 1557. It empowers the Department to continue its robust enforcement of civil rights laws by making clear that the substantive protections of Title VI of the Civil Rights Act of 1964 ("Title VI"), Title IX, the Age Discrimination Act of 1975 ("Age Act"), and Section 504 of the Rehabilitation Act of 1973 ("Section 504") remain in full force and effect.³

This final rule is needed because the Department has determined that portions of the 2016 Rule are duplicative or confusing, impose substantial unanticipated burdens, or impose burdens that outweigh their anticipated benefits. Additionally, two Federal district courts have determined that the Department exceeded its authority in promulgating parts of the regulation, and one has vacated and

remanded those parts of the 2016 Rule. By substantially repealing much of the 2016 Rule, including removing the vacated provisions from the Code of Federal Regulations, the Department reverts to longstanding statutory interpretations that conform to the plain meaning of the underlying civil rights statutes and the United States Government's official position concerning those statutes.

The Department initially estimated the costs from the 2016 Rule at over \$942 million across the first five years. 81 FR 31458–59. This figure, however, significantly underestimated actual costs, according to the Department's current estimates. As estimated now, the costs derived merely from the 2016 Rule's requirement to provide notices and taglines with all significant communications, after accounting for electronic delivery, amount to an average annual burden of \$585 million per year, for a five-year burden of \$2.9 billion. Based on the Department's re-examination of the burden on regulated entities, and after reviewing public comments, the Department has determined that the potential public benefits of imposing such requirements are outweighed by the large costs those requirements impose on regulated entities and other parties.

B. Summary of Major Provisions

(1) Changes to the Section 1557 Regulation

a. Elimination of Overbroad Provisions Related to Sex and Gender Identity

This final rule eliminates certain provisions of the 2016 Rule that exceeded the scope of the authority delegated by Congress in Section 1557. The 2016 Rule's definition of discrimination "on the basis of sex" encompassed discrimination on the basis of gender identity ("an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female"). In line with that definition, the 2016 Rule imposed several requirements regarding medical treatment and coverage on the basis of gender identity. The same definition also encompassed discrimination on the basis of "termination of pregnancy" without incorporating the explicit abortion-neutrality language of 20 U.S.C. 1688 (which some commenters referred to as the Danforth Amendment) in Title IX, and it imposed a high burden of proof on providers to justify offering gynecological or other single-sex medical services.

All of these are essentially legislative changes that the Department lacked the

² 42 U.S.C. 18116.

³ While Section 1557 does not incorporate nondiscrimination provisions by reference to Title VII, it provides that nothing in Title I of the ACA is to be construed as invalidating or limiting the rights, remedies, procedures, or legal standards available under certain civil rights laws, and mentions Title VII specifically. 42 U.S.C. 18116(b).

¹ 81 FR 31375–473 (May 18, 2016) codified at 45 CFR part 92.

authority to make. They purported to impose additional legal requirements on covered entities that cannot be justified by the text of Title IX, and in fact are in conflict with express exemptions in Title IX, even though Title IX provides the only statutory basis for Section 1557's provision against discrimination "on the basis of sex." For this reason, these provisions have already been vacated and remanded by court order. This final rule omits the vacated language concerning gender identity and termination of pregnancy, thereby bringing the provisions of the Code of Federal Regulations into compliance with the underlying statutes and up-to-date as to the effect of the court's order.

The Department also believes that various policy considerations support this action. The 2016 Rule's provisions on sex discrimination imposed new requirements for care related to gender identity and termination of pregnancy that Congress has never required, and prevented covered entities from drawing reasonable and/or medically indicated distinctions on the basis of sex. As a result, those provisions would have imposed confusing or contradictory demands on providers, interfered inappropriately with their medical judgment, and potentially burdened their consciences. By contrast, under this final rule, each State may balance for itself the various sensitive considerations relating to medical judgment and gender identity, within the limits of applicable Federal statutes (which are to be read according to their plain meaning).

b. Clarification of Scope of Covered Entities

In an additional effort to avoid exceeding the Department's statutory authority, this final rule modifies the 2016 Rule's definition of entities covered by Section 1557 in order to align it more closely with the statutory text.

c. Elimination of Unnecessary or Duplicative Language on Civil Rights Enforcement

This final rule also eliminates provisions of the 2016 Rule that, by unnecessarily duplicating or overlapping with existing civil rights law and regulations, were either inconsistent or redundant with existing law and regulations, and so were likely to cause confusion about the rights of individuals and the corresponding responsibilities of providers. This final rule prohibits any covered entity from discriminating on the basis of race, color, national origin, sex, age, and disability, according to the meaning of

these terms in the underlying Federal civil rights statutes that Section 1557 incorporates, and it commits the Department to enforcing these prohibitions through the enforcement mechanisms already available under those statutes' respective implementing regulations. It eliminates the 2016 Rule's definitions of terms and its list of examples of discriminatory practices, as well as its provisions related to discrimination on the basis of association, disparate impact on the basis of sex, health insurance coverage, certain employee health benefits programs, notification of beneficiaries' rights under civil rights laws, designation of responsible employees and adoption of grievance procedures, access granted to OCR for review of covered entities' records of compliance, prohibitions on intimidation and retaliation, enforcement procedures, private rights of action, remedial action, and voluntary action. In all of these matters, this final rule will defer to the relevant existing regulations and the relevant case law with respect to each of the underlying civil rights statutes, as applied to the health context under Section 1557. It will not create, as the 2016 Rule did, a new patchwork regulatory framework unique to Section 1557 covered entities.

d. Elimination of Unnecessary Regulatory Burdens

This final rule modifies provisions of the 2016 Rule that imposed regulatory burdens on covered entities greater than what was needed in order to ensure compliance with civil rights law. Specifically, it eliminates the burdensome requirement for covered entities to send notices and taglines with all significant communications, clarifies that the provision of health insurance, as such, is not a "health program or activity," brings requirements of meaningful access for persons with limited English proficiency (LEP) into conformity with longstanding DOJ and HHS guidance, and permits remote English-language interpreting services to be audio-based rather than requiring them to be video-based.

The final rule retains numerous other provisions of the 2016 Rule that furthered the goal of civil rights compliance without imposing burdens unnecessary to that goal. These include the obligation for covered entities to submit assurances of compliance, as well as most of the 2016 Rule's provisions ensuring access for individuals with LEP and individuals with disabilities.

e. Other Clarifications and Minor Modifications

This final rule modifies the 2016 Rule's discussion of its own relation to other laws, offering a clearer commitment to implement Section 1557 in conformity with the text of the statutes it incorporates, as well as with the text of numerous other applicable civil rights and conscience statutes. It also makes other minor modifications to the regulatory text.

(2) Related and Conforming Amendments to Other Regulations

a. Title IX

Because the Department's failure to incorporate the abortion neutrality language at 20 U.S.C. 1688 (hereinafter "abortion neutrality") and the Title IX religious exemption formed part of the *Franciscan* court's reasoning when it vacated parts of the 2016 Rule, this final rule amends the Department's Title IX regulations to explicitly incorporate relevant statutory exemptions from Title IX, including abortion neutrality and the religious exemption.

b. CMS

Ten provisions in CMS regulations, all of which cover entities that are also subject to Section 1557, have in recent years had language inserted that prohibits discrimination on the basis of sexual orientation and gender identity. In light of this final rule's return to the plain meaning of "on the basis of sex" in the civil rights statutes incorporated under Section 1557, and the overarching applicability of Section 1557 to these programs, the Department here finalizes amendments to those regulations to ensure greater consistency in civil-rights enforcement across the Department's different programs by deleting the provisions on sexual orientation and gender identity.

C. Summary of the Costs and Benefits of the Major Provisions

This final rule is an economically significant deregulatory action. The Department projects that this final rule will result in approximately \$2.9 billion in cost savings (undiscounted) over the first five years after finalization. The Department anticipates that the largest proportion of these estimated savings would result from repealing the 2016 Rule's provisions related to mandatory notices. The Department projects additional savings from eliminating the requirement for OCR to weigh the presence or absence of language access plans, and from repealing provisions that duplicate existing regulatory requirements regarding the

establishment of grievance procedures. The Department estimates that there will be some additional costs to covered entities regarding training and revision of policies and procedures.

The Department believes that the anticipated benefits—which include consistency with Federal statutes, appropriate respect for the roles of Federal courts and Congress, and

reduction or elimination of ineffective, unnecessary, or confusing provisions—far outweigh any costs or burdens that may arise from the changes.

Provision(s)	Savings and benefits	Costs
Sec. 1557: Elimination of Overbroad Provisions Related to Sex and Gender Identity.	For provisions already vacated, eliminating them brings the Code of Federal Regulations in line with current law. For other provisions, eliminating them restores the rule of law by confining regulation within the scope of the Department's legal authority; restores Federalism by leaving to the States decisions properly reserved to them; and removes unjustified burdens on providers' medical judgment.	No costs are anticipated for provisions already vacated, and any possible costs for related provisions are not calculable based on available data.
Sec. 1557: Clarification of Scope of Covered Entities.	Correcting this provision improves the rule of law by interpreting the statute according to its plain meaning as closely as possible.	Costs are not calculable based on available data.
Sec. 1557: Elimination of Unnecessary or Duplicative Language on Civil Rights Enforcement.	Eliminating these provisions reduces duplication, inconsistency, and possible confusion in the Department's civil rights regulations, making it easier for covered entities and individuals to know their respective responsibilities and rights.	The Department estimates \$275.8 million of costs in the first year for revision of policies and procedures, along with corresponding retraining of employees. (These costs encompass the next listed set of provisions as well.)
Sec. 1557: Elimination of Unnecessary Regulatory Burdens.	Eliminating these provisions reduces unnecessary, unjustified, or excessive burdens on health providers, as well as excessive and confusing paper notices for patients. This will make healthcare more affordable and accessible for Americans and is estimated to save \$585 million per year over the first five years.	See above.
Sec. 1557: Other Clarifications and Minor Modifications.	Amending these provisions improves the rule of law by ensuring that regulations remain subject to statutory protections for conscience and other civil rights, and otherwise contributes to the goals of the other regulatory changes listed above.	No costs are anticipated, and any possible costs are not calculable based on available data.
Title IX regulations, related amendment.	This amendment ensures the rule of law by clarifying that Title IX regulations are subject to the statute's own abortion-neutrality language and religious exemption.	No costs are anticipated, and any possible costs are not calculable based on available data.
CMS regulations, conforming amendments.	These amendments restore the rule of law by confining regulations within the scope of their legal authority, and ensure consistency in civil-rights enforcement across the Department's different programs.	Costs are not calculable based on available data.

II. Background

On May 18, 2016, the Department finalized a regulation implementing Section 1557 of the ACA. The Department had received 402 comments⁴ in response to a related request for information in 2015, and 24,875 comments⁵ in response to the relevant Notice of Proposed Rulemaking, 80 FR 54172–221 (“2015 NPRM”).

Multiple States and private plaintiffs challenged the 2016 Rule in Federal district courts in Texas and North Dakota on the grounds that it violated Federal laws, including the Administrative Procedure Act (“APA”) and the Religious Freedom Restoration

Act (“RFRA”).⁶ On December 31, 2016, the U.S. District Court for the Northern District of Texas preliminarily enjoined, on a nationwide basis, portions of the 2016 Rule that had interpreted Section 1557 to prohibit discrimination on the basis of gender identity and termination of pregnancy.⁷

On May 2, 2017, the Department of Justice, on behalf of HHS, filed a motion for voluntary remand to reassess the reasonableness, necessity, and efficacy of the enjoined provisions. On May 24, 2019, HHS issued a notice of proposed rulemaking (“the proposed rule” or “the 2019 NPRM”) to amend the 2016 Rule, as well as its regulations effectuating Title IX,⁸ and to make conforming amendments to certain

nondiscrimination provisions of CMS regulations⁹ covered by Section 1557. On June 14, 2019, HHS published the proposed rule in the **Federal Register**¹⁰ and accepted public comment for 60 days thereafter.

On October 15, 2019, upon motion of the plaintiffs, and adopting the reasoning from its preliminary injunction order, the U.S. District Court for the Northern District of Texas vacated and remanded the “the unlawful portions” of the 2016 Rule that had been subject to that order.¹¹ On

⁴ <https://www.regulations.gov/docket?D=HHS-OCR-2013-0007>. The comment docket identifies 162 submissions, but some submissions to the docket aggregated multiple comments.

⁵ <https://www.regulations.gov/docket?D=HHS-OCR-2015-0006>. The comment docket identifies 2,188 submissions, but some submissions to the docket aggregated multiple comments, and “the great majority” of comments were not electronic but were submitted by mail as part of “mass mail campaigns organized by civil rights/advocacy groups.” 81 FR 31376.

⁶ Complaint, *Franciscan All., Inc. v. Burwell*, No. 7:16-cv-00108–O (N.D. Tex. Aug. 23, 2016); *Religious Sisters of Mercy v. Burwell*, No. 3:16-cv-386 (D.N.D. filed Nov. 7, 2016); *Catholic Benefits Association v. Burwell*, No. 3:16-cv-432 (D.N.D. filed Dec. 28, 2016).

⁷ See *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016).

⁸ 20 U.S.C. 1681 *et seq.*; 45 CFR part 86 (Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance).

⁹ 42 CFR 438.3, 438.206, 440.262, 460.98, 460.112; 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230.

¹⁰ 84 FR 27846 (June 14, 2019) (“Nondiscrimination in Health and Health Education Programs”).

¹¹ *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 945 (N.D. Tex. Oct. 15, 2019) (“Since the Court concludes that ‘the Rule’s conflict with its incorporated statute—Title IX—renders it contrary to law under the APA,’ the appropriate remedy is *vacatur*. Order 38, ECF No. 62. Accordingly, the Court VACATES and REMANDS the unlawful portions of the Rule for Defendants’ further consideration in light of this opinion and the Court’s December 31, 2016 Order.”; *id.* at 947 (“The Court ADOPTS its prior reasoning from the

November 21, 2019, the court clarified that “the Court vacates only the portions of the Rule that Plaintiffs challenged in this litigation,” namely, “insofar as the Rule defines ‘On the basis of sex’ to include gender identity and termination of pregnancy The remainder of 45 CFR part 92 remains in effect.”¹²

The Department herein finalizes the proposed rule without change, except as set forth below, after careful consideration of and responses to public comments.

III. Response to Public Comments on the Proposed Rule

The Department received 198,845 comments in response to the proposed rule during the public comment period.¹³ Commenters included Members of Congress, State and local governments, State-based Exchanges, tribes and tribal governments, healthcare providers, health insurers, pharmacies, religious organizations, civil rights groups, non-profit organizations, and individuals, among others.

A. General Comments

Comment: Several commenters, including healthcare providers, explained that although they support nondiscrimination in healthcare and equal access to healthcare for all patients, they have difficulty complying with the parameters of the 2016 Rule. They believe that civil rights protections should be balanced against the burdens they create. Accordingly, these commenters support the proposed regulation as it limits the burdens imposed on providers.

Response: The Department agrees with these commenters’ support of nondiscrimination in healthcare and intends to robustly enforce the civil rights authorities. The Department is also cognizant of unduly burdensome regulations. For example, the 2016 Rule did not anticipate some costs to covered entities that range from hundreds of millions to billions of dollars as a result of notice and tagline requirements. Therefore, this final rule seeks to alleviate certain burdens on covered entities while still enforcing the nondiscrimination requirements of Title

VI, Title IX, the Age Act, and Section 504.

Comment: Some commenters said the proposed rule would stabilize services for individuals with disabilities and create a more equitable distribution of health services.

Response: The Department agrees. This final rule maintains appropriate protections for individuals with disabilities and will provide clarity for providers and individuals.

Comment: Several commenters expressed concern that eliminating discrimination protections in Section 1557 will cause confusion about patients’ rights and remove access to administrative remedies that were previously available.

Response: The Department recommits itself in this rule to enforcing nondiscrimination on the basis of all categories protected by statute. The Department is confident that the clarity associated with maintaining longstanding prohibitions on discrimination under Title VI, Title IX, the Age Act, and Section 504, and their respective implementing regulations, will outweigh any initial confusion stemming from the change.

Comment: Some commenters noted the extensive process involved in developing the 2016 Rule, which included a request for information, the 2015 NPRM, and the 2016 Rule, with the Department considering more than 24,875 public comments. Such commenters suggested this proposed rule unnecessarily reopens the 2016 Rule and ignores the reasoned process that the Department had previously completed. Also, a commenter asked why the Department did not publish a request for information before the proposed rule. Others stated that the proposed rule relies disproportionately on a single district court case, *Franciscan Alliance*,¹⁴ to justify a new interpretation of sex. The commenters go on to suggest that the Department relied exclusively on *Franciscan Alliance* to open up the entire 2016 Rule for edits while ignoring numerous other court cases that come to opposing conclusions regarding sex discrimination.¹⁵

¹⁴ *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016).

¹⁵ Commenters cited *Boyd v. Conlin*, 341 F. Supp. 3d 979 (W.D. Wisc. 2018) (holding Wisconsin’s use of transgender exclusions in its state employee health insurance plan constituted sex discrimination in violation of Section 1557 and Title VII); *Flack v. Wis. Dept. of Health Servs.*, 328 F. Supp. 3d 931, 951 (W.D. Wis. 2018); *Prescott v. Rady Children’s Hospital-San Diego*, 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017) (finding Section 1557’s plain language bars gender identity discrimination); *Tovar v. Essential Health*, 342 F. Supp. 3d 947, 957 (D. Minn. 2018) (same).

Response: On December 31, 2016, the *Franciscan Alliance* court preliminarily enjoined the 2016 Rule’s gender identity and termination of pregnancy provisions on a nationwide basis, finding them unlawful under the APA and RFRA. A few weeks later, a second Federal district court preliminarily stayed enforcement of the 2016 Rule against two other plaintiffs, citing the *Franciscan* decision.¹⁶ Because of the nationwide preliminary injunction, the Department could not enforce certain provisions from the 2016 Rule. In the process of reconsidering the 2016 Rule, and consistent with applicable Executive Orders and deregulatory priorities, the Department examined the rule more broadly and concluded that, for the reasons explained in the 2019 NPRM, the 2016 Rule had significantly underestimated the costs and burdens it imposed. Because Section 1557 authorizes, but does not require, the creation of new implementing regulations, the Department considered it appropriate to repeal certain portions of the 2016 Rule and enforce Section 1557 using the underlying regulations the Department has used to enforce the relevant civil rights statutes identified in Section 1557. The Department also considered the Executive Branch’s most recent statements concerning the interpretation of statutory provisions that prohibit discrimination on the basis of sex.

The Department published its proposed rule in the **Federal Register** on June 14, 2019, opening a two-month public comment period. The Department received nearly 200,000 comments for its review. Through this public comment period, the public was given a full opportunity to provide the Department with information regarding the proposal. It is not necessary to engage in an additional solicitation of public comments through a request for information before the notice of proposed rulemaking. The Department also reviewed the 2016 Rule record and its public comments in considering this final rule.

Through this rulemaking, the Department has provided a comprehensive rationale for this final rule. The 2019 NPRM summarized the Department’s legal authority to change the 2016 Rule along with policy rationales for doing so. The quantum of evidence necessary to justify rescinding provisions of a rule is not greater than the evidence needed for issuing it in the

preliminary injunction (ECF No. 62) and now HOLDS that the Rule violates the APA and RFRA. Accordingly, the Court VACATES and REMANDS the Rule for further consideration.”)

¹² Order, *Franciscan Alliance*, No. 7:16–cv–00108–O *2 (N.D. Tex. filed Nov. 21, 2019).

¹³ See <https://www.regulations.gov/docket?D=HHS-OCR-2019-0007>. The comment docket identifies 155,966 submissions, but some submissions to the docket aggregated multiple comments. HHS estimates the disaggregated number of comments to be 198,845.

¹⁶ *Religious Sisters of Mercy v. Burwell*, Nos. 3:16–cv–386 & 3:16–cv–432 (D.N.D. Order of January 23, 2017). See 84 FR 27848.

first place.¹⁷ Moreover, after publication of the proposed rule, the Court in *Franciscan Alliance* issued its final judgment vacating and remanding the unlawful portions of the 2016 Rule for the Department's further consideration. The Department has considered that *vacatur*, along with the legal authorities and policy rationales discussed in the NPRM and this preamble, and more thoroughly calculated the costs and effects of the notice and taglines requirements, to arrive at this final rule. Specific responses to comments on its various provisions, including on sex discrimination, are found below.

Comment: Some commenters expressed concern that the updated Section 1557 regulations will have unintended consequences and costs for healthcare providers and individuals seeking healthcare and insurance, particularly pertaining to access standards for people with LEP and communication-based disabilities, in part because the regulatory drafting period was shorter than the period for the 2016 Rule.

Response: The Department has spent several months carefully reviewing comments, providing responses to them in this rule, and finalizing the proposed rule. The Department is leaving several substantive provisions of the 2016 Rule unchanged or substantially unchanged. The changes largely consist of excisions of regulatory text as opposed to the addition of new text, so it is unsurprising that the regulatory drafting period was shorter than the period for the 2016 Rule. In many instances where new or modified regulatory text was proposed, such text was based on existing guidance or regulatory text. The Department considers this to be an adequate process and a sufficient period of time to engage in such rulemaking.

This final rule maintains vigorous protections for people with LEP and communication-based disabilities, as discussed in detail below, and the Department intends to continue robust enforcement of those protections.

Comment: Several commenters indicated that the cost savings cited in the proposed rule are unsupported or based on insufficient data. Several commenters also contend that the proposed rule ignores the costs to individuals, especially LEP individuals, who will allegedly encounter additional barriers to accessing healthcare as a result of the proposed changes. Some commenters were concerned that the proposed rule would help eliminate access to a wide range of affordable

preventive health services, including cancer screenings, contraception, and reproductive health services. The commenters believe this loss of access will largely be caused by the proposed changes to the definition of sex discrimination. Many commenters expressed concern that the proposed rule would remove civil rights protections for a number of vulnerable groups, including LEP individuals, LGBT individuals, individuals with disabilities, and women seeking reproductive healthcare. Such commenters state that the removal of these protections would, in turn, result in even greater health disparities for these vulnerable populations. Some commenters stated that the proposed rule would lead to increased discrimination in healthcare, which would lead people to delay or forego healthcare and would result in adverse health outcomes and greater overall healthcare costs to individuals. Some of these commenters note that based on these anticipated increased disparities, the proposed rule is effectively encouraging discrimination.

Response: This final rule leaves in place all statutory civil rights protections for vulnerable groups. Cost savings are treated in the Regulatory Impact Analysis below, which discusses the data, estimates, and assumptions used to support its calculations. Potential health disparities or other alleged costs to individuals or vulnerable groups, including those due to discrimination or barriers to access, are discussed in the relevant sections below (e.g., potential costs to LEP individuals are discussed in comments on those sections of the regulation that deal with national-origin discrimination and/or LEP, while potential costs relating to the gender identity provision are discussed in comments on the section regarding "discrimination on the basis of sex").

Comment: Many commenters expressed their belief that this proposed rule diverges from the current body of civil rights laws. These commenters believe that limiting protections based on gender identity, termination of pregnancy, and LEP, runs contrary to civil rights protections.

Response: Current civil rights laws and their protections are discussed, respectively, in the relevant sections below (e.g., civil rights law on gender identity is discussed in the section on "discrimination on the basis of sex," because the 2016 Rule had classified gender identity discrimination as a form of sex-based discrimination).

Comment: Some commenters stated that civil rights protections should not

be eliminated because of compliance costs faced by covered entities, and that such balancing runs contrary to the Affordable Care Act and the Administrative Procedure Act. Such commenters argue that if the Department determines that particular protections are too costly or onerous, it should advance more limited protections rather than eliminating them entirely.

Response: This final rule does not, and could not, repeal or eliminate specific protections under any of the four civil rights statutes referenced in Section 1557, and it does not remove the protections provided by the implementing regulations for those statutes.

The Department has, however, chosen to reduce some excessive burdens that were applied to covered entities by the 2016 Rule, but were not required by Section 1557, where the relevant civil rights protections could be enforced using the underlying regulations without the unnecessary burdens imposed by the 2016 Rule.

Comment: Commenters stated that the Department exceeded its authority by proposing this rule. Some commenters indicated that the Department's positions as advanced in the proposed rule are not worthy of deference under the framework established in *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984), because the proposed rule is contrary to clear congressional intent and is inconsistent with the agency's past policies concerning sex protections. Many of these commenters assert that the changes set forth in the proposed rule run contrary to the requirements of the ACA, pointing to 42 U.S.C. 18114 (Section 1554), which states that the Department shall not "promulgate any regulation that—(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services. . . ." These commenters also state that the Department is attempting to make a legislative change through an administrative action. Some commenters contend that the proposed rule runs contrary to the general intent of the ACA, namely that all individuals should be provided access to healthcare.

Response: The 2016 Rule tried to make essentially legislative changes through administrative action, and those changes were rightly held to be in violation of the APA. The Department does not exceed its authority by rescinding the portions of the 2016 Rule that exceeded the Department's authority. The Department also does not

¹⁷ See 84 FR 27850; *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 514–15 (2009).

violate Section 1554 of the ACA by not including the gender identity and termination of pregnancy provisions in this final rule, which were not supported by the text of the underlying civil rights laws incorporated in Section 1557, and in addition were vacated by court order.

With respect to both Sections 1554 and 1557, the Department interprets the ACA by the plain meaning of its text, and as will be shown below, this final rule brings the Department's Section 1557 regulations in line with a proper understanding of the ACA's text. Parts of the 2016 Rule exceeded the Department's authority under the ACA, and this final rule formally eliminates those portions from the Code of Federal Regulations. The Department believes this approach adheres more closely to the text of the statutes referenced in Section 1557, along with the regulations that the Department has used to implement those statutes for decades. Other parts of the 2016 Rule are being modified or repealed in order to save providers from unnecessary burdens not required by the ACA, so that they are better able to achieve the statute's goal of providing healthcare access to all Americans. Such a reconsideration and elimination of certain regulatory provisions, particularly regulations that the ACA itself did not require to be issued, neither "creates" unreasonable regulatory barriers nor impedes timely access to healthcare. If it were otherwise, Section 1554 would essentially serve as a one-way ratchet, preventing the Department from ever reconsidering a regulation that could be characterized as improving access to healthcare in some sense, regardless of the other burdens such regulation may impose on access to health care. The Department's approach in this final rule is also consistent with the Ninth Circuit's recent interpretation of Section 1554: "[t]he most natural reading of § 1554 is that Congress intended to ensure that HHS, in implementing the broad authority provided by the ACA, does not improperly impose regulatory burdens on doctors and patients."¹⁸ As explained throughout the preamble, the Department's rule avoids precisely such burdens by bringing the section 1557 regulations into alignment with the longstanding requirements of the applicable civil rights laws and their implementing regulations (thereby also avoiding additional conscience burdens that the 2016 Rule potentially imposed) and by removing notice and taglines requirements that imposed unjustified

burdens on the healthcare system as a whole (some of which would likely have been passed on to individuals).

Comment: Commenters said that Section 1557 should be construed broadly because throughout the ACA, Congress prohibited a variety of forms of discrimination, such as against pre-existing conditions and combating health disparities. Commenters also indicated that the ACA is intended to reduce the cost of healthcare discrimination against the poor, so the Section 1557 rule should implement cost sharing and other insurance requirements.

Response: In the ACA, Congress labeled several provisions other than 1557 as prohibiting discrimination¹⁹ in healthcare, but did not incorporate those other provisions of the ACA into Section 1557. Those other provisions are different from the civil rights provisions set forth in Section 1557 in substance, implementation, and enforcement. This final rule commits the Department to robust enforcement of the nondiscrimination grounds applicable under Section 1557.

Comment: A commenter contended that the Department provided little or no legal, policy, or cost-benefit analysis along with the proposed rule and combined too many changes into a single rule. Some commenters claimed the proposed rule is arbitrary, capricious, and contrary to law, is inconsistent with the agency's mission, and lacks reasoned explanations justifying the policy reversals. Other commenters stated that HHS failed to account for the extensive history of healthcare discrimination, and provided no contrary data to counter the original factual findings in the 2016 Rule. Furthermore, they said that individuals have reasonably placed their reliance upon the Federal government to protect their civil rights as explained in the 2016 Rule.

Response: The Department provided ample legal, policy, and cost-benefit analysis for the proposed rule and provides additional support here for the final rule.²⁰ The Department proposed changes to the provisions of the 2016 Rule because that rule exceeded the Department's authority under Section 1557, adopted erroneous and inconsistent interpretations of civil rights law, caused confusion, imposed

unjustified and unnecessary costs, and conflicted with applicable court decisions. It is unfortunate that, by administrative action, the 2016 Rule may have unreasonably raised expectations about nondiscrimination protections that are not found in the underlying statutes, but this final rule cannot be held responsible for that. The Department gave extensive reasons for its changes in the 2019 NPRM, and gives further reasons in response to comments below. The public comment process provided adequate opportunity to present legal, policy, and cost-benefit analyses, all of which were considered in finalizing this rule, as discussed herein.

The Department also updates and discusses the regulatory impact analysis based on comments and data received. While there are still some questions addressed by this final rule where robust data are unavailable, were not found by the Department, or have not been brought to the Department's attention, the Department is allowed to engage in rulemaking even where the impact of a rule change is difficult or impossible to quantify. The Department has diligently considered the relevant and significant data of which it is aware.

There is no artificial limit on the number of changes a proposed rule may contain—or on the number of parts in the Code of Federal Regulations that can be addressed in a rulemaking. This final rule contains many fewer changes than the 2016 Rule did, and it substantially streamlines the existing 1557 regulation as opposed to enlarging it. Its inclusion of conforming changes to various CMS regulations still gives the final rule a size and scope that is well within the range of other significant proposed rules.

Comment: Several commentators stated that the proposed rule's language that Title IX and Section 1557 must be "exercised with respect for State sovereignty" runs contrary to the Supreme Court's decision that Congress has the authority to prohibit discrimination in commercial activity.

Response: This final rule does not, nor does the Department intend to, remove any protection against State action that Congress has provided by statute. It also does not deny States the ability to provide protections that exceed those required by Federal civil rights law. The reference to State sovereignty simply refers to the Department's intention to protect the States by respecting their sovereignty to the extent that doing so does not infringe on Federal law.

Comment: One commenter noted that, after the 2016 Rule was passed, the

¹⁸ *California v. Azar*, No. 19–15974, 2020 WL 878528, at *18 (9th Cir. Feb. 24, 2020) (en banc).

¹⁹ See, e.g., ACA Section 2701 ("discriminatory premium rates"); Section 2716 ("discrimination based on salary"); Section 2705 ("discrimination against individual participants and beneficiaries based on health status"); Section 2716 ("discrimination in favor of highly compensated individuals").

²⁰ See 45 FR at 27875–88.

Department released resources and educational materials, including fact sheets, to explain the 2016 Rule. The commenter requested that the Department release similar resources and educational materials following the finalization of this rule.

Response: The Department is providing the responses to comments contained in this preamble to clarify issues and answer questions concerning this final rule. Furthermore, the Department continues to be committed to providing resources and educational materials to explain civil rights requirements and to assist covered entities with compliance with civil rights statutes and the regulations thereunder, including this regulation.

B. Section 1557 Regulation, Subpart A: General Requirements and Prohibitions

The Department proposed changes to the Section 1557 rule at 45 CFR part 92 to be composed of Subpart A on general requirements and prohibitions, and Subpart B on specific applications related to disability nondiscrimination and language access.

(1) Proposed Repeal of Definitions in § 92.4 of the 2016 Rule

Comments: A commenter contended that eliminating the definitions section in the Section 1557 Regulation would cause confusion, misinterpretation, and inconsistency of terms among the regulations that currently reference or otherwise rely on the underlying definitions in the 2016 Rule.

Response: In significant part, the definitions section of the 2016 Rule duplicates definitions already incorporated into the Section 1557 regulation by reference, and hence creates either inconsistency or redundancy. In other cases, the 2016 Rule contained definitions inconsistent with the text of applicable statutes; indeed, on those grounds, a Federal district court vacated the 2016 Rule's definition of "on the basis of sex" insofar as it encompassed gender identity and termination of pregnancy. The Department will continue to enforce Section 1557 using HHS regulations for the underlying civil rights statutes. Many of these regulations have definition sections and operate based on longstanding understandings of how the laws are enforced.

Comments: Some commenters argued that eliminating the phrases "covered entities" and "health program or activities" would allow many plans and programs to be exempt from the Section 1557 regulation. Other commenters stated that the existing definitions

provide clarity and consistency for covered entities. Another commenter stated that the proposed rule would limit Section 1557's application to the specific program or activity that receives Federal assistance, rather than a healthcare entity's entire operations.

Response: See below, under "Scope of Application in Proposed § 92.3," for a discussion of the entities subject to this final rule.

Comment: Some commenters asked the Department to retain the definition of "auxiliary aids and services" concerning effective communication for individuals with disabilities. They also asserted that the Department has altered important definitions related to effective communication, without explanation or acknowledgement. While some commenters appreciated the Department's efforts to incorporate many of the current definitions of Title II of the Americans with Disabilities Act ²¹ ("ADA"), some claim the Department has erred in tracking the language of those definitions.

Response: The Department is not required to track ADA definitions in its Section 1557 regulation. This final rule applies many definitions based on those found in the ADA or its regulations (including "disability" and "auxiliary aids and services"), technical definitions and standards under the ADA, and Uniform Federal Accessibility Standards as promulgated; as discussed below, it also departs from ADA definitions in certain cases. Additionally, this final rule retains effective communication standards for individuals with disabilities under § 92.102; these provisions are drawn from regulations promulgated by the Department of Justice implementing Title II of the ADA. ²² Specific definitions and provisions related to individuals with disabilities are discussed below.

The proposed rule apprised the public of the language the Department sought to finalize in the rule, gave the Department's reasons for changes relative to the 2016 Rule, and provided an opportunity to comment on the proposed language.

Comment: Some commenters opposed the proposed removal of the definition for "national origin," saying it would lead to confusion among providers and recipients as to what constitutes discrimination on the basis of national origin.

Response: The term "national origin" is not specifically defined in Title VI or in HHS's implementing regulation, but

the Department has appropriately enforced the prohibition on national origin discrimination under Title VI for decades in accord with relevant case law. In implementing this final rule, the Department intends to enforce vigorously the prohibition on national origin discrimination in a manner consistent with the current interpretation under Title VI, including under *Lau v. Nichols*, as discussed below. ²³

Comment: Some commenters asserted that the removal of definitions weakens protections for LEP individuals and signals a lack of priority for enforcement by the Department.

Response: As discussed below, meaningful access for individuals with LEP is a key component of the national origin protections under Title VI and Section 1557, and will be well protected by this final rule. The streamlining of this regulation through the elimination of largely redundant definitions will in no way impede the Department's strong commitment to meaningful access for LEP individuals.

Summary of Regulatory Changes: The Department finalizes its repeal of § 92.4 of the 2016 Rule without change. Additional comments concerning the definitions of sex, gender identity, and other specific definitions are discussed in more detail below.

(2) General Changes to 2016 Rule

a. Purpose of Regulation, Revising § 92.1 of the 2016 Rule

The Department proposed to revise the statement of the purpose of the regulation in § 92.1 from "implement[ation]" of Section 1557 to "provid[ing] for the enforcement" of Section 1557. 84 FR at 27861.

Comment: A commenter said this change in language allows the Department to minimize its involvement in ensuring that nondiscrimination protections are effective.

Response: This is the opposite of the Department's intention. This final rule's title and citation to statutory authority already make clear that it is implementing Section 1557. By changing the rule's language from "implement" to "provide for the enforcement of," the Department simply means to emphasize, in terms accessible to a lay audience, that it will fully enforce Section 1557 and the underlying nondiscrimination laws as they fall within the jurisdiction of the Department, according to the text of those laws and their implementing regulations.

²¹ 42 U.S.C. 12101 *et seq.*

²² 42 U.S.C. 12311; *see also* 28 CFR 35.160–164.

²³ *Lau v. Nichols*, 414 U.S. 563 (1974).

b. Effective Date

The Department proposed that the effective date of the revised regulation be 60 days after publication of the final rule, in order to relieve significant regulatory burdens, particularly the taglines requirements.²⁴ The 2016 Rule's effective date was July 18, 2016 (60 days after publication of the final rule), with the exception of the provisions on health insurance and benefit design, which went into effect on January 1, 2017 (the first day of the first plan year following the effective date).²⁵ The new rule does not include a different effective date for health insurance and benefit design.

Comment: Commenters asked that the Department make the effective date several months prior to the plan open enrollment period that occurs between November 1 and December 15, in order for the covered entities to have sufficient time to incorporate the regulatory changes into the next plan year.

Response: The Department has endeavored to issue this final rule sufficiently in advance of the plan year cycle, so that plans can incorporate the regulatory changes into the next plan year. Moreover, because this final rule generally relieves regulatory requirements rather than adding them, it should be easier for issuers to incorporate such changes into the plans they will offer for the next plan year.

Comment: Commenters stated that it is inappropriate to finalize the change to the definition of sex as it relates to Section 1557 in light of current litigation before the Supreme Court, which may be resolved by the end of the court's term or before. These commenters note that the Supreme Court's ruling in *R.G. & G.R. Harris Funeral Homes v. EEOC & Aimee Stephens*²⁶ will determine whether Title VII of the Civil Rights Act of 1964 extends sex discrimination protections to transgender status, and that the ruling may apply to the definition of sex under Title IX as well. Accordingly, these commenters urge the Department to wait until the Supreme Court decides *Harris Funeral Homes* before publishing a rule that deals with the same subject matter, or allow for commenters to comment again once the case has been decided.

Response: The Department acknowledges the commenters' point of view but respectfully disagrees. The U.S. government has taken the position

in *Harris* and other relevant litigation that discrimination "on the basis of sex" in Title VII and Title IX does not encompass discrimination on the basis of sexual orientation or gender identity.²⁷ The Department shares that position and is permitted to issue regulations on the basis of the statutory text and its best understanding of the law and need not delay a rule based on speculation as to what the Supreme Court might say about a case dealing with related issues. The Department also agrees with the *Franciscan Alliance* ruling, according to which the 2016 Rule's extension of sex-discrimination protections to encompass gender identity was contrary to the text of Title IX and hence not entitled to *Chevron* deference.²⁸ Moreover, to the extent that a Supreme Court decision is applicable in interpreting the meaning of a statutory term, the elimination of a regulatory definition of such term would not preclude application of the Court's construction.

The Department continues to expect that a holding by the U.S. Supreme Court on the meaning of "on the basis of sex" under Title VII will likely have ramifications for the definition of "on the basis of sex" under Title IX.²⁹ Title VII case law has often informed Title IX case law with respect to the meaning of discrimination "on the basis of sex,"³⁰ and the reasons why "on the basis of sex" (or "because of sex," as used in Title VII) does not encompass sexual orientation or gender identity under Title VII have similar force for the interpretation of Title IX. At the same time, as explained below, the binary biological character of sex (which is ultimately grounded in genetics) takes on special importance in the health context. Those implications might not be fully addressed by future Title VII rulings even if courts were to deem the categories of sexual orientation or gender identity to be encompassed by the prohibition on sex discrimination in Title VII. As a result, the Department considers it appropriate to finalize this rule, which does not define sex, but relies on the plain meaning of the term under Title IX, and does so in the health

context within which the Department applies Title IX under Section 1557.

Comment: Commenters disagreed with the Department's reliance on the litigation and court order in *Franciscan Alliance* to justify revisiting the rule, because the injunctive order was not permanent, was allegedly limited to enforcement actions of HHS, and does not require new rulemaking, and because other litigants have intervened in the case to defend the 2016 Rule. Some commenters stated that although the U.S. District Court in *Franciscan Alliance* ruled against the 2016 Rule's definition of sex, other courts have come to conclusions that suggest the opposite, and HHS is not required to alter Department-wide policy based on the injunction in *Franciscan Alliance*. Others argued that the Department improperly relied on one legal decision that they said conflicts with the clear weight of case law. Another commenter stated it would be inappropriate to publish any new rule before a final ruling in *Franciscan Alliance*, as the case is being appealed.

Response: Nearly three years after the preliminary injunction, and after the comment period on the proposed rule had concluded, the court in *Franciscan Alliance* issued a final ruling vacating the 2016 Rule "insofar as the Rule defines 'On the basis of sex' to include gender identity and termination of pregnancy," and remanding the Rule for further consideration.³¹ This final ruling is binding on the Department despite the appellate proceedings still pending in that case: The Department's Section 1557 regulation, as currently operative, does not contain the 2016 Rule's definition of "on the basis of sex" to encompass gender identity and termination of pregnancy. The *Franciscan Alliance* court's 2016 injunction gave the Department good cause to reconsider the 2016 Rule, but neither the injunction nor the *vacatur* was the Department's only reason for revising it, as the proposed rule made clear and as the Department's responses to comments in this preamble reiterate. Nothing in the appellate litigation prohibits the Department from finalizing this rule, which it does for the reasons given in this preamble. As for the weight of case law, it is discussed below with respect to the respective provisions of this final rule.

Comment: One commenter noted that the Department's announcement of the proposed rule on May 24, 2019 had stated that a fact sheet explaining the changes in the proposed rule would be

²⁷ As noted elsewhere in this preamble, it has been the consistent position of the federal government that "on the basis of sex" under Section 1557 does not encompass sexual orientation, including the decision in the 2016 Rule not to include sexual orientation in the definition of that term. See 81 FR at 31390.

²⁸ *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 945 (N.D. Tex. Oct. 15, 2019) (incorporating its previous ruling at 227 F. Supp. 3d at 685–87).

²⁹ See 84 FR 27855.

³⁰ See, e.g., *Yusuf v. Vassar Coll.*, 35 F.3d 709, 714 (2d Cir. 1994).

³¹ Order, *Franciscan Alliance*, No. 7:16-cv-00108-O *2 (N.D. Tex. filed Nov. 21, 2019).

²⁴ 84 FR at 27888.

²⁵ 81 FR at 31378.

²⁶ *R.G. & G.R. Harris Funeral Homes, Inc. v. EEOC*, 139 S. Ct. 1599 (2019).

provided in Spanish. However, no such fact sheet has been provided. Accordingly, the commenter requested that the comment period be extended until 60 days after the fact sheet is published in Spanish.

Response: The proposed rule itself did not purport to offer information in Spanish, and the Department was not under a legal obligation to offer a separate fact sheet or to translate it. The Department's press release indicated that a fact sheet, separately created in connection with the press release, would be translated. That is not a basis for reopening the comment period on the proposed rule, because the proposed rule provided the public with adequate notice and a 60-day public comment period, which were legally sufficient.

c. Severability

The Department proposed to repeal the provision in § 92.2(c) of the 2016 Rule stating that if a regulatory provision in this part were held invalid or unenforceable on its face or as applied to a specific person or circumstances, the provision should be construed to the maximum effect permissible by law and be severable such that it would not affect other persons or circumstances that are dissimilar.

Comment: Commenters asked the Department to add a severability provision to the final rule. Specific points recommended included severing repeal of the provisions related to the notices and taglines, and/or the changed scope of applicability, from the sex discrimination provisions. Commenters said that the Supreme Court case *K-Mart Corp. v. Cartier, Inc.*, 108 S. Ct. 1811 (1988), would allow the Department to sever the changes in the taglines provision from the proposed rule and implement those changes even in the event that a court delays or suspends the proposed rule.

Response: In part due to these comments, the Department has decided not to finalize the proposal to eliminate the severability provision from the 2016 Rule. Instead the Department will retain that severability provision, but has moved it to § 92.3(d), because § 92.3 is now the provision addressing the application of the rule. This change will be discussed again below in the discussion of § 92.3.

d. Summary of Regulatory Changes

For the reasons described in the proposed rule, and having considered the comments received, the Department finalizes the proposed § 92.1 without change, and confirms that the effective date of this final rule will be 60 days

after its publication in the **Federal Register**.

(3) Scope of Application in Proposed § 92.3; Repeal of § 92.208

The Department proposed to repeal § 92.2 of the 2016 Rule, and instead address the scope of application of Section 1557 in a new § 92.3. 84 FR at 27862–63. The Department also proposed to repeal § 92.208 of the 2016 Rule, which had expanded the scope of the Section 1557 statutory provision to apply to certain employee health benefits programs.³²

a. Generally

Comment: Commenters argued the Department did not provide a reasoned legal, policy, or cost-benefit analysis to support the repeal of § 92.208, which hindered their ability to provide meaningful comments as required by the APA. The commenters maintained that the Department's comparison of § 92.208 to Title IX³³ was flawed, in part because HHS's Title IX regulation does not apply to all bases of discrimination or many of the same covered entities as addressed under Section 1557. Some commenters noted that employees deserve protection from discrimination in employer-sponsored plans.

Response: As seen below in the response to a similar comment on § 92.207, § 92.208 appears in the NPRM in a list of sections of the 2016 Rule that "are duplicative of, inconsistent with, or may be confusing in relation to the Department's preexisting Title VI, Section 504, Title IX, and the Age Act regulations."³⁴ The Department repeals § 92.208 for reasons similar to those given at greater length below in discussing § 92.207: It seeks to relieve regulatory burden and possible confusion by enforcing the relevant nondiscrimination statutes through their existing regulations.

The Department is not aware of data and methods available to make reliable estimates of all economic impacts predicted by various commenters. The Department's estimates of regulatory impact are discussed below.

Comment: Commenters stated that individuals protected by Section 1557,

³² Compare 45 CFR 92.208 (employer liability for discrimination in employee health benefit programs in Section 1557) with 45 CFR 86.56 (discrimination on the basis of sex in fringe benefits under Title IX). The enforcement Memorandum of Understanding (MOU) between OPM and the Department, signed by OCR on 11 January 2017, is moot upon publication of this final rule.

³³ 84 FR at 27869, n.148 (comparing § 92.208 with 45 CFR 86.56 (discrimination on the basis of sex in fringe benefits under Title IX)).

³⁴ 84 FR 27869.

particularly individuals with disabilities, frequently experience discrimination in healthcare. Commenters expressed concerns that the narrowed application would reduce the number of covered entities and would lead to more discrimination, lack of care, and adverse health outcomes, which they argued is contrary to the stated Congressional intent and purpose of the ACA to expand access to and end discrimination in health insurance. Several State and local government commenters expressed concern that the proposed rule would negatively affect public health in their States and increase costs to States due to more people seeking care through government-funded programs, such as Medicaid.

Conversely, other commenters were supportive of the proposed rule's revised scope and agreed that the 2016 Rule was far too broad in its application. They concurred that narrowing the scope of application would help rein in the regulatory excess and burden of the 2016 rule.

Response: The Department must follow the text of the ACA. To the extent that Congressional intent and purpose are relevant, they are best determined by looking to the plain meaning of the statutory text. This final rule will enforce Section 1557's discrimination requirements against the entities that Congress intended them to be enforced against. The Department's specific reasoning in interpreting Section 1557's scope of coverage follows.

b. § 92.3(a): Covered Programs and Activities

The Department proposed in § 92.3(a) that, except as otherwise provided in part 92, the Section 1557 rule will apply to (1) any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by the Department; (2) any program or activity administered by the Department under Title I of the ACA; or (3) any program or activity administered by any entity established under Title I of the ACA.

Comment: Some commenters opposed removing the full definition of "Federal financial assistance" from the 2016 Rule and replacing it with the limited text under proposed § 92.3(a)(1). They stated that the lack of specificity could lead to ambiguity and confusion. Commenters further asserted that the proposed rule was inconsistent with the Department's recently promulgated *Protecting Statutory Conscience Rights in Health*

Care (“2019 Conscience Rule”),³⁵ which included an expansive definition of “Federal financial assistance.”³⁶

Response: The Department concludes it is appropriate to have a definition of Federal financial assistance that mirrors Section 1557’s statutory text to include “credits, subsidies, or contracts of insurance.” In addition, the definitions applicable under the preexisting civil rights statutes still apply, and the Department believes it is more appropriate to apply those existing definitions than to maintain the ones in the 2016 Rule. Section 1557 says the enforcement mechanisms provided for and available under the underlying civil rights statutes shall apply, and the Department believes operating under those mechanisms and the definitions that have long been applicable to them, along with the language the Department retains in this final rule, is appropriate moving forward. The 2019 Conscience Rule was based on different statutes.

Comment: Some commenters opposed the proposed rule’s exclusion of Federal financial assistance that the Department “plays a role” in providing or administering, which had been included in the 2016 Rule’s definition of Federal financial assistance. Commenters argued that the statute applies to programs or activities administered by “an Executive Agency” and thus should not be limited to HHS. In particular, they objected to the result that qualified health plans (QHPs) would no longer be covered under the rule on the basis that HHS plays a role in administering tax credits. The commenters argued that this interpretation is contrary to a plain reading of the statute, which not only uses the broad term “Federal financial assistance” (without a modifier to limit it to assistance directly administered by HHS), but also expressly includes “credits” as part of Federal financial assistance. Further, some commenters noted that the Department took an inconsistent and broader approach in its Conscience Rule, wherein HHS exerts jurisdiction over statutes and funding also administered by the U.S. Departments of Labor and Education.

Response: The statutory text of Section 1557 refers simply to “any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance.” Because the Section 1557 regulation applies only to the Department, the 2015 NPRM had reasonably sought to limit its scope to

Federal financial assistance from the Department, leaving other Departments to enforce Section 1557 within their own sphere.³⁷ In the 2016 Rule, however, wishing to encompass tax credits administered under Title I, the Department expanded the rule’s scope to encompass “Federal financial assistance that the Department plays a role in providing or administering.”³⁸ The Department now regards this expansion as overbroad. While Section 1557 still applies to any health program or activity receiving any Federal financial assistance, this final rule prescribes enforcement only by the Department and within the Department’s jurisdiction. The Department does not consider it appropriate in this final rule to apply its provisions to any programs that the Department “plays a role in” administering.

Commenters’ concerns about covering QHPs are misplaced: These plans remain subject to this rule because they are sold on the Exchanges established under Title I of the ACA (see § 92.3(a)(3) of this final rule). This final rule only prescribes enforcement of Section 1557 by the Department and within the Department’s jurisdiction, so the Department believes it is appropriate for this regulation to not include activities funded or administered solely by other Federal agencies even if Section 1557 may apply in those instances.

The 2019 Conscience Rule (as stated above) relied on different statutes than the Section 1557 rule, and the Department drafts its regulations as appropriate for the underlying statutes.

Comment: Commenters disapproved of proposed § 92.3(a)(2), which would limit the rule’s application in the context of HHS-administered programs or activities to only those administered under Title I of the ACA. Commenters argued that this interpretation is inconsistent with the statutory text of Section 1557, which applies to “any program or activity administered by an Executive Agency or any entity established under this title [sc., Title I].” (emphasis added). Commenters argued the proposed § 92.3(a)(2) would incorrectly apply “under this title” to

modify both phrases. Furthermore, they argued that the Department did not provide an adequate rationale for its interpretation in the proposed rule.

Response: As explained in the 2019 NPRM, the statutory text of Section 1557 applies to “any program or activity” administered by an Executive Agency or Title I entities, but does not include the modifier “health” with respect to those programs or activities.³⁹ In the 2016 Rule, the Department limited its application by adding “health” to “programs or activities” because the Department recognized that Section 1557 was not intended to apply to every program or activity administered by every Executive Agency, whether or not it related to health.⁴⁰ The 2016 Rule acknowledged implicitly what the Department now states more clearly: The grammar of the relevant sentence in the Section 1557 statutory text concerning limits to its scope is less clear than it could have been. In resolving the sentence’s ambiguity, however, the Department no longer agrees with the 2016 Rule’s decision to add a limiting modifier (*i.e.*, “health”) that Congress did not include in the statutory text. Instead, the Department concludes that Congress had already placed a limitation in the text of Section 1557 by applying the statute to any program or activity administered by an Executive Agency “under this title” (meaning Title I of the ACA), as well as to any program or activity administered by an entity established under such title. The Department believes that either this interpretation of the statutory text, or the 2016 Rule’s addition of the modifier “health,” is necessary in order to make sense of the statutory text; this final rule offers a technical reading of the text that is at least as reasonable as the 2016 Rule’s addition of a word not present in the text of the statute.

Comment: Commenters argued that the proposed interpretation to limit coverage to HHS Title I programs or activities would exclude a number of important programs and activities operated by HHS and is inconsistent with Section 504’s application to “any program or activity conducted by an

³⁵ *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 FR 23170–01 (2019).

³⁶ 45 CFR 88.2.

³⁷ 80 FR 54173 (“Section 1557 applies to all health programs and activities, any part of which receives Federal financial assistance from any Federal Department. However, this proposed rule would apply only to health programs and activities any part of which receives Federal financial assistance from HHS. This narrowed application is consistent with HHS’ enforcement authority over such health programs and activities, but other Federal agencies are encouraged to adopt the standards set forth in this proposed rule in their own enforcement of Section 1557.”).

³⁸ 81 FR 31467, 31384; *cf.* 80 FR 54216.

³⁹ 42 U.S.C. 18116(a) (applying Section 1557, in relevant part, to “any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).”). *See also* 84 FR at 27861–62 (discussing the Department’s statutory interpretation).

⁴⁰ 45 CFR 92.2 (applying the final rule, in relevant part, to “every health program or activity administered by the Department; and every health program or activity administered by a Title I entity”) (emphasis added).

Executive Agency.”⁴¹ They point out that HHS’s Section 504 regulation applies to “all programs or activities” conducted by HHS and all its components, including CMS, HRSA, CDC, and SAMHSA.⁴² Further, commenters stated that excluding non-Title I HHS-administered programs and activities, contrary to Section 504, will result in confusion and cause illogical results, whereby recipients would be covered by Section 1557 but the agencies administering the program would not be covered. For example, State Medicaid programs would be subject to Section 1557, but CMS, which oversees those Medicaid programs, would not be covered.

Response: Section 1557 is a nondiscrimination statute under the ACA, which uniquely applies to healthcare, whereas Section 504 is a statute of general applicability. Section 1557 incorporates Section 504’s prohibited grounds of discrimination but not its scope: Section 1557’s scope differs from that of the underlying statutes. For instance, Section 504 does not include “contracts of insurance” in its definition of Federal financial assistance,⁴³ but this final rule follows the text of Section 1557 by including “contracts of insurance” within Federal financial assistance.⁴⁴ With respect to CMS, it is covered under this final rule to the extent that it either administers health programs and activities receiving Federal financial assistance or administers programs and activities under Title I. In addition, it is important to note that, as a federal agency, CMS has long been subject to various constitutional and statutory prohibitions on discrimination.

c. § 92.3(b): Scope of the Term “Health Program or Activity”

The Department proposed in § 92.3(b) to clarify that “health program or activity” encompasses all of the operations of entities “principally engaged in the business of providing healthcare” that receive Federal financial assistance. The Department proposed to further clarify that for any entity not principally engaged in the business of providing healthcare, such entity’s operations are subject to the Section 1557 Rule only to the extent any such operation receives Federal

financial assistance provided by the Department.

Comment: Commenters opposed limiting application of the rule when the entity is not principally engaged in the business of providing healthcare. Commenters argued that this would dramatically limit the scope of the rule and is contrary to Congressional intent and the plain meaning of the statute, which covers “any health program or activity, any part of which is receiving Federal financial assistance. . . .” Commenters stated that the entire entity receiving Federal financial assistance should be covered, not just the portion receiving funding. Commenters also argued the new framework would cause uncertainty and confusion for covered entities, which would have to clarify the extent of their own compliance, and also would make it harder for consumers to enforce their rights because they would have difficulty determining which entities and which portion of their programs or activities are subject to the rule. Commenters contended this uncertainty could result in lack of access to care, increased health disparities, and increased uncompensated care, all of which would increase overall healthcare costs.

Some commenters stated that the rule incorrectly incorporates the Civil Rights Restoration Act (CRRA)⁴⁵ into Section 1557. Commenters argued that the CRRA predates the ACA; nothing in the CRRA’s text applies it to future statutes or Section 1557; Congress did not incorporate the CRRA into the Section 1557 statute; and Section 1557 itself is more expansive than the laws amended by the CRRA. Therefore, they say, a broader definition of covered programs and activities should apply to include all health insurers as covered entities. Others argued that the proposed rule’s application of the CRRA contravenes the approach taken by Congress in the CRRA. They stated that Congress made clear in the CRRA that if any part of a program or activity receives Federal financial assistance, the entire program or activity must comply with the applicable civil rights laws. Thus, the commenters argued that the proposed rule’s limited application when entities are not principally engaged in the business of healthcare, to cover only the specific operation that receives Federal financial assistance, is contrary to the CRRA. Another commenter stated that incorporating the CRRA into Section 1557 would be subject to judicial review, to the extent the Department relies on Section 1557’s references to

“grounds” and “enforcement mechanisms” of the underlying statutes to do so, because the Supreme Court held in *Consolidated Rail Corp. v. Darrone* that a statute’s incorporation of another statute’s enforcement mechanisms does not necessarily incorporate its substantive law.⁴⁶

Conversely, other commenters were supportive of reducing regulatory burden by limiting application of the rule in this way. They stated that the 2016 Rule defined “covered entities” far too broadly, and that narrowing the scope will help rein in the regulatory excess of that rule. Commenters explained that healthcare entities often provide a variety of services and products, such as insurance coverage for life, disability, or short-term limited duration insurance coverage, and third-party administrative services, which do not receive Federal financial assistance. These commenters agreed that Section 1557 is intended to apply only to those programs receiving Federal funding and not to other parts of the entity’s businesses or products when an entity is not principally engaged in the business of providing healthcare.

Response: Section 1557 explicitly incorporates statutes amended by the CRRA, and in this final rule the Department is aligning Section 1557’s definition of “health program or activity” with the standard articulated in the CRRA in order to provide clarity and consistency. The CRRA clarified the scope of nondiscrimination prohibitions under the civil rights statutes that Section 1557 incorporates. For example, with respect to the health sector, it applied those prohibitions to all health programs or activities receiving Federal financial assistance, but not to all providers of health insurance: It applied “program or activity” to cover all of the operations of an entity only when that entity is “principally engaged in the business of providing . . . health care”⁴⁷ This final rule clarifies that the term “health program or activity” used in Section 1557 should be understood in light of the CRRA’s limitations on the term “program or activity” as applied to statutes on which Section 1557 relies. As for *Consolidated Rail Corp. v. Darrone*, Congress specifically and intentionally

⁴¹ 29 U.S.C. 794 (applying to “any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service”).

⁴² 45 CFR, part 85.

⁴³ 45 CFR 84.3(h).

⁴⁴ 42 U.S.C. 18116(a).

⁴⁵ Public Law 100–259, 102 Stat. 28 (Mar. 22, 1988).

⁴⁶ See *Consolidated Rail Corp. v. Darrone*, 465 U.S. 624, 635 (1984) (holding that Section 504’s incorporation of the “remedies, procedures, and rights” set forth in Title VI did not mean that Section 504 incorporated Title VI’s substantive limitations on actionable discrimination).

⁴⁷ See, e.g., CRRA § 3(a) (adding § 908(3)(A)(ii) to Title IX of the Education Amendments of 1972 (codified at 20 U.S.C. 1687(3)(A)(ii)).

overturned that case through the passage of the CRRRA.⁴⁸

The 2016 Rule also articulated a standard for “health program or activity” that relied upon the “principally engaged” prong of the CRRRA, which was contested neither before nor after that rule’s publication. In the regulatory text, the 2016 Rule defined “health program or activity” to apply to all operations of an entity only when it is principally engaged in providing or administering health services, health insurance coverage, or other health coverage.⁴⁹ The 2016 Rule preamble clarified that if an entity is not principally engaged in providing health benefits, the Department would apply the rule to its Federally funded health programs and activities.⁵⁰

The Department believes that by specifying the degree to which the Section 1557 regulation covers entities not principally engaged in the business of providing healthcare, this final rule more clearly and consistently applies the CRRRA’s limitations on “health program or activity” across the regulation. The Department agrees with commenters who suggest that in doing so this final rule also advances its goal of reducing regulatory burdens under the ACA in furtherance of Executive Order 13765.

Comment: Commenters argued that limiting the application of the rule to only the portion of the health program or activity that receives Federal financial assistance for entities not principally engaged in the business of providing healthcare is not consistent with the Department’s application of Title VI as set forth in HHS’s 2003 LEP guidance. This guidance provided that Title VI applies to all parts of a covered entity receiving Federal financial assistance, not just the portion receiving Federal funds.⁵¹

Response: As a policy guidance document, the Department’s LEP guidance cannot be used to create binding standards by which the

Department will determine compliance with existing regulatory or statutory requirements.⁵² Accordingly, the scope of application as set forth under the CRRRA and this final rule would prevail over any conflicting text in the Department’s LEP guidance.

d. § 92.3(c) Health Insurance and Healthcare

The Department proposed in § 92.3(c) to state that an entity principally or otherwise engaged in the business of providing health insurance would not be considered to be principally engaged in the business of providing healthcare, and on that sole basis, subject to the Section 1557 regulation. The proposed rule sought comment on whether it should define “healthcare” in the rule according to the statutes cited in the proposed rule.

Comment: Several commenters supported the distinction between entities principally engaged in the business of providing healthcare and those principally engaged in the business of providing health insurance. As one commenter stated, “[p]roviding for healthcare is not providing healthcare.” Other commenters were opposed to this distinction. They argued that it is not consistent with Section 1557’s statutory text or the proposed regulatory text at § 92.3(a)(1), both of which specifically include “contracts of insurance” as an example of Federal financial assistance. They also stated that this limited application is not consistent with Congressional intent to expand access to healthcare and create new nondiscrimination protections in health insurance.

Some commenters argued that health insurance is inextricably linked with the provision of healthcare. They pointed out that the statutory definition of “healthcare” relied upon in the proposed rule is unrelated to either the ACA, health insurance, or discrimination, and thus is not intended for or relevant to Section 1557 or health insurance.⁵³ Further, they argued that the definition of “health insurance coverage” referenced in the proposed rule, 42 U.S.C. 300gg–91, actually

bolsters the argument that health insurance includes healthcare, as it defines “health insurance coverage” to include “benefits consisting of *medical care* (provided directly, through *insurance* or reimbursement, or otherwise and including items and services paid for as medical care)” (emphasis added). They also pointed out that definitions in 42 U.S.C. 300gg–91 are most relevant to Section 1557 because Title I of the ACA relied upon this section for definitions.

Response: The CRRRA defined “program or activity” in the underlying statutes to apply to all of an entities’ operations when it is principally engaged in the business of providing “healthcare.” On the other hand, the 2016 Rule expansively interpreted Section 1557’s application to “health programs or activities” to include all operations of entities that “provide health insurance coverage or other health coverage,” whether or not they provided healthcare. Prior to the 2016 Rule, the Department had not interpreted the CRRRA’s term “healthcare” to cover the operations of health insurance issuers (as such).

Commenters are correct that Section 1557 includes “contracts of insurance” as a type of Federal financial assistance. The Department agrees that health programs or activities that receive contracts of insurance from the Federal government are covered entities under Section 1557. But this does not mean that health insurers, as such, are health programs or activities.

The Department pointed to 5 U.S.C. 5371, as well as to 45 CFR 160.103, in order to support its conclusion that the plain meaning of “healthcare” differs from insurance. And although 42 U.S.C. 300gg–91 explicitly encompasses payment, “group health plans,” and “definitions relating to health insurance” specifically, it should not be taken out of context: It defines “medical care” as “amounts paid for” certain medical services, which is an appropriate definition in the health insurance field but not in the healthcare field generally. (When a doctor provides “medical care,” she is not providing “amounts paid for” medical services—she is providing the services themselves.) Other portions of 42 U.S.C. 300gg–91 also support the distinction between healthcare and health insurance: It says that “health insurance coverage means benefits consisting of medical care,” where “medical care” is defined as “amounts paid for . . . the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body,” or

⁴⁸ See *McMullen v. Wakulla Cty. Bd. of Cty. Commissioners*, 650 F. App’x 703, 705 (11th Cir. 2016), citing S. Rep. No. 100–64, at 2 (1988), as reprinted in 1988 U.S.C.A.N. 3, 3–4.

⁴⁹ 81 FR at 31467. In the proposed rule, the Department disagreed with the 2016 Rule’s usage of “health services, health insurance coverage, or other health coverage” as overbroad and inconsistent with the statutory text of the CRRRA that uses the term “healthcare.” See 84 FR at 27862–63. However, the Department agrees with the 2016 Rule’s limitation based on whether the entity is principally engaged.

⁵⁰ 81 FR at 31385–86, 31430–32.

⁵¹ 68 FR 47311, 47313 (Aug. 8, 2003) (“Coverage extends to a recipient’s entire program or activity, i.e., to all parts of a recipient’s operations. This is true even if only one part of the recipient receives the Federal assistance.”).

⁵² See U.S. Dept. of Justice, Memorandum of the Office of the Attorney General, Prohibition on Improper Guidance Documents (Nov. 16, 2019), <https://www.justice.gov/opa/press-release/file/1012271/download>; U.S. Dept. of Justice, Memorandum of the Office of the Associate Attorney General, Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases (Jan. 25, 2018), <https://www.justice.gov/file/1028756/download>.

⁵³ See 84 FR at 27862 (citing the definition of “health care” at 5 U.S.C. 5371). Commenters noted that this definition pertains to Federal personnel pay rates.

“amounts paid for transportation primarily for and essential to medical care” in the primary sense just defined, or “amounts paid for insurance covering medical care” in either the primary sense just defined or the secondary sense of transportation for medical care.⁵⁴ It does not say that health insurance is healthcare, and it twice relies on the commonsense distinction between medical care proper and the health insurance that covers and pays for such care. It thus supports the Department’s view that a health insurer is principally engaged in the business of providing coverage for benefits consisting in healthcare, which is not the same as the business of providing healthcare. This final rule brings the 1557 regulation’s scope of coverage closer to the plain meaning of the 1557 statute, especially as read in light of the CRRA’s definition of “program or activity.”

Comment: Commenters were concerned that § 92.3(c) would result in exempting many of the plans, products, and operations of most health insurance issuers, such as self-funded group health plans, the Federal Employees Health Benefits (FEHB) Program, third-party administrator services, or short-term limited duration insurance plans. Commenters feared this would allow health insurance issuers to conduct their other activities in a discriminatory manner. Several commenters were particularly concerned about excluding short-term limited duration insurance plans because these plans have been known to engage in discriminatory practices based on disability, age, and sex.

Other commenters, in contrast, supported the proposed revisions. They stated the 2016 Rule was overly expansive, created an un-level playing field, and resulted in disincentives for issuers to participate in HHS-funded programs, such as offering QHPs or Medicare Advantage plans. This resulted in Section 1557’s covering products that Congress explicitly excluded from the rest of the ACA, such as excepted benefits and short-term limited duration insurance plans. Commenters argued it was unlikely that Congress intended Section 1557 to regulate the same plans it had excluded from the ACA.

Response: The Department agrees with commenters who stated that the overly broad reach of the 2016 Rule subjected many insurance products that were not intended to be covered by the ACA to burdensome regulation, inconsistent with Congressional intent.

In the proposed rule, the Department stated that Section 1557 does not apply to short-term limited duration insurance as such, but only if it were offered by an entity for which all of the entity’s activities are encompassed by Section 1557, or if such insurance received Federal financial assistance.⁵⁵ Under this final rule, where short-term limited duration insurance (1) is offered by an entity that is not principally engaged in the business of providing healthcare, and (2) does not receive Federal financial assistance, the protections of Section 1557 would not apply to it. The Department will robustly enforce the nondiscrimination requirements for QHPs under Title I of the ACA, for Exchange plans established by the ACA, and for any other insurance plans that Section 1557 covers. The reasons that this final rule does not cover FEHB plans are discussed in the response to the next comment.

Comment: The Department received comments related to the exclusion of employer plans and excepted benefits as a result of § 92.3(c). Several commenters objected to the exclusion of self-funded group health plans under the Employee Retirement Income Security Act of 1974 (ERISA) and the Federal Employees Health Benefits (FEHB) Program. Commenters argued that FEHB plans should be covered as a contract of insurance with the Federal government. Some suggested that employer group health plans, including self-funded plans, receive substantial Federal financial assistance in the form of favorable income tax treatment and thus should be covered.

Other commenters strongly supported excluding employer plans. Commenters noted that employers and group health plans are already subject to other Federal laws that prohibit discrimination, and that few employer-sponsored plans receive Federal financial assistance. They stated that the 2016 Rule’s broad coverage exceeded statutory authority, encumbered the design and operation of employer group

health plans, invited litigation regarding plan benefits, and increased the potential for costly new mandates, all of which were likely to increase healthcare costs for employers and employees alike without adding any additional protections against discrimination. Some commenters expressed support for the provision that third-party administrators of self-funded group health plans would no longer be subject to Section 1557 merely because other portions of their business receive Federal funding.

Some commenters requested further clarification by recommending that the regulatory text at proposed § 92.3(c) be revised to specify that other types of plans should not be considered entities principally engaged in the business of providing healthcare, including self-funded or fully insured group health plans under ERISA; self-funded or fully insured group health plans not covered under ERISA that are sponsored by either governmental employers (“government plans”) or certain religious employers (“church plans” or “denominational plans”); and benefit plans and programs excepted under the ACA.⁵⁶

Response: The Department continues to take the position that FEHB plans are not covered under this rule. Even if FEHB plans were considered “contracts of insurance,” as suggested by some commenters, they still would not fall under the scope of this rule because the contract would be with the Office of Personnel Management (OPM), which operates the FEHB Program, not with the Department. As noted above, this final rule does not extend the Department’s enforcement authority to a covered entity that is not principally engaged in the business of providing healthcare to the extent of its operations that do not receive financial assistance from the Department.

The Department agrees that this final rule will accomplish the Department’s goal of reducing regulatory burden. The Department declines to offer further examples of non-covered entities in the regulatory text, as the rule’s existing parameters are intended to broadly address different entities. To the extent that employer-sponsored group health plans do not receive Federal financial assistance and are not principally engaged in the business of providing healthcare (as set forth in the rule), they would not be covered entities. The same analysis would apply to employer-sponsored plans not covered by ERISA, such as self-insured church plans or

⁵⁵ The Department notes by way of background that, subsequent to publication of the proposed rule, the U.S. District Court for the District of Columbia granted summary judgment for the Department, upholding its most recent rulemaking on short-term limited duration insurance. See *Short-Term, Limited-Duration Insurance*; Final Rule, 83 FR 38212 (August 3, 2018). The August 2018 final rule largely restored the long-standing definition for short-term limited duration insurance to the definition that was in effect from 1997 to 2016. The Court held that the restored definition was not arbitrary or capricious, finding that “Congress clearly did not intend for the [ACA] to apply to all species of individual health insurance.” *Association for Community Affiliated Plans v. U.S. Department of Treasury*, 392 F. Supp. 3d 22, 45 (D.D.C. 2019), *appeal filed* July 30, 2019.

⁵⁶ See 42 U.S.C. 300gg–91(c) (defining excepted benefits).

⁵⁴ 42 U.S.C. 300gg–91(b)(1), (a)(2).

non-Federal governmental plans, as well as to excepted benefits.

Comment: Some commenters said that the proposed rule created confusion about whether QHPs are subject to the rule. Others requested clarification on the proposed rule's application to products offered through the Exchange. Others requested clarification on whether stand-alone dental plans and catastrophic plans, which are also sold through the Exchanges established under Title I, are covered under the rule. Another commenter requested confirmation that the proposed rule would not apply to individual or small-group market health insurance coverage that complies with the ACA but is sold outside of the Exchanges, regardless of whether the parent organization also offers on-Exchange QHPs. Others requested clarification as to how the rule would apply when one health insurance plan includes multiple types of enrollees, including subsidized Exchange enrollees, unsubsidized Exchange enrollees, and off-Exchange enrollees. The comments expressed concern that enrollees in the same plan deserved the same level of nondiscrimination protection and that the same standard should be applied.

Response: Health insurance products are often complex. While the Department provides general responses below in an attempt to clarify application of the rule, OCR will always engage in an individualized fact-based analysis when determining the extent of its jurisdiction over these or any other such products.

A QHP would be covered by the rule because it is a program or activity administered by an entity established under Title I (*i.e.*, an Exchange), pursuant to § 92.3(a)(3). A QHP could also be subject to Section 1557 if it were a recipient of Federal financial assistance, but as stated above, the premium tax credits that the Department plays a role in administering would no longer serve to bring an entity under the jurisdiction of this Section 1557 regulation.

Stand-alone dental plans and catastrophic plans offered through the Exchanges would similarly be subject to § 92.3(a)(3), as these plans are administered by an Exchange, which is an entity established under Title I.

Regarding ACA-compliant plans sold off-Exchange, because a health insurance issuer is not principally engaged in the business of providing healthcare, its operations would be subject to this rule only for the portion that receives Federal financial assistance. The issuer's components (*e.g.*, off-Exchange plans) that do not

directly receive Federal financial assistance would not be subject to this rule.

Where a health insurance plan includes multiple types of enrollees, the Department would have to review the specific circumstance, but generally speaking, if a QHP is subject to Section 1557, this rule would apply consistently for all enrollees in the plan.

Comment: The Department received comments related to how the rule would apply to Medicare- and Medicaid-related products. One commenter asked whether the proposed limitation under § 92.3(c) would mean that Section 1557 would no longer apply to health insurance plans managed through Medicare and Medicaid.

A few commenters requested clarification on whether the proposed rule would apply to Employer Group Waiver Plans (EGWPs) and Medicare Part D Retiree Drug Subsidy (RDS) plans, or the employers that sponsor the plans. Commenters argued that applying the rule to these plans could disincentivize employers from sponsoring them and urged that the plans be exempt from the rule. Alternatively, one commenter requested that the Department exempt employer sponsors of "800 series" EGWPs, which are offered by Medicare Advantage Organizations (MAOs) or Part D Plan sponsors (PDP sponsors), because the employer is not the entity that receives funding from HHS. Finally, some commenters objected to excluding Medicare Part B from the rule.

Response: To be covered by the rule, a particular entity would have to satisfy one of the applicability requirements set forth in § 92.3. Entities that receive Federal funding through the Department's Medicare Part C (Medicare Advantage), Medicare Part D, or Medicaid programs would be subject to Section 1557 as recipients of Federal financial assistance. This would include Medicare Advantage plans, Medicaid managed care plans, EGWPs, or RDS plans, to the extent that they receive Federal financial assistance.

Pending further details, an employer that does not directly contract with CMS but offers an "800 series" EGWP through a MAO or PDP sponsor would not appear to be subject to this rule under this analysis because the employer does not receive the Federal financial assistance; meanwhile, the health insurance issuer offering the EGWP would be subject to the rule for its EGWP plan, due to receipt of either Medicare Part C or Part D funding.

As for Medicare Part B, it is not Federal financial assistance.⁵⁷ This remains unchanged from the 2016 Rule, which also determined that Medicare Part B was not Federal financial assistance under Section 1557.

Comment: Some commenters requested that this final rule be accompanied by explicit applicability guidance so that employers and plans could be able to ascertain if the final rule impacts their business.

Response: The Department seeks to provide sufficient clarity in this final rule. If OCR receives substantial questions about the rule's applicability after publication, OCR will consider issuing additional clarification, consistent with applicable law regarding issuance of sub-regulatory guidance.⁵⁸

e. Summary of Regulatory Changes

For the reasons given in the proposed rule, and having considered comments received, the Department finalizes the proposed § 92.3, and repeal of § 92.2 of the 2016 Rule, without change, except that, as discussed in an earlier section of this preamble, and after considering comments on the issue, the Department is not finalizing the proposed repeal of § 92.2(c) concerning severability, but is retaining that provision and has moved it to § 92.3(d).

(4) Nondiscrimination Requirements in Proposed Revisions to § 92.2, and Repeal of § 92.8(d), 92.101, 92.206, 92.207, 92.209, and Appendix B of the 2016 Rule

The Department proposed to repeal § 92.8(d), 92.101, 92.206, 92.207, and Appendix B of the 2016 Rule (which includes repealing notice and taglines

⁵⁷ 45 CFR pt. 80 App A, No. 121; <https://www.hhs.gov/civil-rights/for-individuals/faqs/what-qualifies-as-Federal-financial-assistance/301/index.html>. See also 81 FR at 31383, 31385; 84 FR at 27863 (discussing the applicability of the rule to Medicare Part B and clarifying in footnote 100 that "[t]he Department believes that the Federal financial assistance does not include Medicare Part B under the Social Security Act. See 2 CFR 200.40(c) (Uniform Administrative Requirement, Cost Principles, and Audit Requirements for Federal Awards); 45 CFR 75.502(h) (Uniform Administrative Requirement, Cost Principles, and Audit Requirements for HHS Awards).").

⁵⁸ See, *e.g.*, Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication, 84 FR 55239 (Oct. 9, 2019); Executive Order 13891 on Promoting the Rule of Law Through Improved Agency Guidance Documents, 84 FR 55235 (Oct. 9, 2019); U.S. Dept. of Justice, Memorandum of the Office of the Associate Attorney General, Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases (Jan. 25, 2018), <https://www.justice.gov/file/1028756/download>; U.S. Dept. of Justice, Memorandum of the Office of the Attorney General, Prohibition on Improper Guidance Documents (Nov. 16, 2019), <https://www.justice.gov/opa/press-release/file/1012271/download>.

provisions), and instead address nondiscrimination requirements in a new § 92.2. The Department proposed to repeal provisions that made applicable across all protected categories those particular requirements, prohibitions, or enforcement mechanisms that had previously applied only to particular circumstances.

The Department requested comments on all aspects of the proposed rule. The Department also specifically requested comment on any unaddressed discrimination on the basis of race, color, or national origin as applied to State and Federally-facilitated Exchanges, with any detailed supporting information. And the Department requested comment on whether, and if so how, the proposed rule addresses clarity and confusion over compliance requirements and the rights of persons protected against discrimination on the basis of race, color, national origin, sex, disability, or age.

The Department received many comments on these proposed changes. The Department will first discuss comments concerning each of the grounds in Section 1557: Race, color, national origin, disability, age, and sex. Then other grounds of discrimination will be discussed, followed by assessment of claims of discriminatory conduct when multiple grounds of discrimination are alleged. Comments concerning disability and LEP protections will be addressed below in the section on Subpart B of the Section 1557 rule.

a. Discrimination on the Basis of Race, Color, or National Origin

i. Generally

Comment: The Department received support for its commitment to continued enforcement of race, color, and national origin protections. Commenters stated that these characteristics are clear and simple to distinguish, contrasting them with gender identity, which is fluid and more difficult to define.

Response: The Department appreciates the support for its continued commitment to the enforcement of protections against discrimination on the basis of race, color, and national origin. The Department agrees that gender identity as a category is difficult to define. This is not, however, the Department's reason for not viewing gender identity as a protected category under Section 1557. The Department enforces statutory prohibitions on discrimination on the basis of race, color, national origin, age, disability,

and sex discrimination because they are set forth in the text of statutes incorporated into Section 1557, and gender identity is not set forth as a protected category in those statutes.

Comment: Commenters contended that the proposed changes, including repeal of § 92.101 and the specific discrimination it prohibited, will lead to confusion among individuals and lead healthcare providers to discriminate based on race, color, and national origin. Commenters recommended that the Department retain clear, strong language prohibiting healthcare providers from discriminating based on race, color and national origin.

Response: This final rule's § 92.2 retains clear, strong language prohibiting discrimination on the basis of race, color, or national origin. Covered entities are still required to provide the Department with an assurance, and, pursuant to the underlying civil rights regulations, to post notices, that they do not so discriminate and are in compliance with Federal civil rights law. If the Department learns of confusion among covered entities or individuals as to their civil rights, it will consider issuing further guidance as needed.

Comment: Some commenters contended that the proposed changes will negatively impact women of color, who (according to these commenters) disproportionately rely on the short-term health plans that this final rule does not cover, and are more likely to experience pregnancy-related issues that will cause them to suffer from the rollback of termination of pregnancy protections.

Response: For reasons detailed below, this final rule (a) does not generally apply to short-term limited duration health insurance and (b) only covers termination of pregnancy to the extent permitted by Title IX's abortion-neutrality language, as required by the relevant statutes. The Department will vigorously enforce the prohibitions on discrimination based on race or sex, including under disparate impact analysis with respect to race discrimination as provided for in the relevant Title VI regulations, but the Department remains bound by the limits of the statutes enacted by Congress. The Department's Office of Minority Health also supports outreach to diverse populations and those facing particularized or disproportionate health challenges.

Comment: One commenter expressed concern that the changes in the proposed rule will have a negative impact on access to health screenings and vaccinations for patients. The

commenter stated that removal of nondiscrimination requirements for many health insurance providers will leave these populations with little recourse if health insurance providers rescind coverage for preventative health services.

Response: Because this final rule continues to commit the Department to robust enforcement of its prohibitions on discrimination on the basis of race, color, national origin, sex, age, and disability, the Department does not anticipate that it will impede any population's access to preventive care and vaccinations, which (under separate provisions of the ACA) must be covered without cost sharing for group health plans and health insurance issuers offering group or individual health insurance coverage.⁵⁹

ii. Repeal of Notice and Taglines Provisions at § 92.8(d) and Appendix B of the 2016 Rule

The Department proposed to repeal § 92.8(d) of the 2016 Rule, which required a nondiscrimination notice and taglines in all significant communications from covered entities, and also proposed to repeal the sample taglines notice in Appendix B to Part 92. 84 FR at 27857–60. The Department stated its assumption that this will correspondingly ease the burden of the LEP provision in CMS regulations at 45 CFR 155.205(c)(2)(iii)(A), which deemed compliance with the LEP provisions of the Section 1557 regulation to constitute compliance with CMS's requirements.⁶⁰

The Department specifically sought comment to identify “significant communications” under the 2016 Rule sent by covered entities that include a notice and taglines but had not been considered by the analysis in the proposed rule, as well as the estimated annual volume of such communications. The Department also requested comment on which communications are significant in healthcare.

Comments: Some commenters stated that the removal of the 2016 Rule's notice and taglines provisions will result in LEP beneficiaries having less knowledge of available language assistance services and that they will likely rely more on family members to provide oral interpretation.

Response: The regulations of the underlying statutes referred to in Section 1557 (Title VI, Section 504, Title IX, and the Age Act) have long mandated that covered entities provide

⁵⁹ See 42 U.S.C. 300gg–13.

⁶⁰ 84 CFR 27887, n. 240, and 27881.

a notice of nondiscrimination.⁶¹ This final rule maintains that requirement. Moreover, it continues to require covered entities to provide taglines whenever such taglines are necessary to ensure meaningful access by LEP individuals to a covered program or activity. It removes only the unduly broad, sometimes confusing, and inefficient requirement that all significant communications contain taglines. This requirement caused significant unanticipated expenses, as discussed in the regulatory impact analysis (RIA) below. Moreover, as discussed below, § 92.101 of this final rule reiterates longstanding criteria to help covered entities conduct an individualized assessment of their program and ensure meaningful access by persons with LEP, and retains the 2016 Rule's prohibition on covered entities' requiring an LEP individual to provide his or her own interpreter or relying on an accompanying adult to interpret or facilitate communication (except in limited circumstances).

Comment: Some commenters disagreed with the Department's proposal to make conforming amendments to the CMS requirements placed on Health Insurance Exchanges and Qualified Health Plan (QHP) issuers at 45 CFR 155.205. These commenters argued that the CMS requirements do not rely on the 2016 Rule's taglines provisions, nor does the 2016 Rule prevent the implementation of additional requirements in more specific programs, such as Medicaid and Medicare. Others agreed with the Department's proposal, raising concerns about CMS's requirements at 45 CFR 155.205, which state that Exchanges and QHP issues are only "deemed" in compliance with the CMS requirements "if they are in compliance with" the 2016 Rule's taglines provisions. These commenters argued that if the notice and taglines provisions are removed, the CMS compliance provision will cross-reference a repealed rule, which would require QHP issuers and Exchanges to comply with CMS's taglines rule instead. The CMS mandate for 15 taglines for the CMS list of critical documents is arguably as burdensome as the 2016 Rule's taglines provisions; therefore, these commenters argue that any benefit in efficiency yielded by the repeal of the 2016 Rule's taglines provisions would be lost for Exchanges and QHP issuers. These commenters suggest amending the 2016 Rule's provisions to state that there is no

specific taglines requirement under Section 1557 and that a covered entity's compliance under applicable Federal and State laws will be considered under Section 1557's LEP meaningful access standards.

Response: The provision at 45 CFR 155.205(c)(2)(iii)(A) and the similar requirement placed on QHP issuers (see HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 FR 10750, 10788 (Feb. 27, 2015)), have not been directly amended in this regard. Nevertheless, as the Department stated in the proposed rule,⁶² both of those requirements depend on or refer to the taglines requirements repealed in this final rule. As a result, covered entities are deemed compliant with those particular taglines requirements due to this final rule. Specifically, 45 CFR 155.205(c)(2)(iii)(A) sets forth taglines requirements and then states, "Exchanges, and QHP issuers that are also subject to § 92.8 of this subtitle, will be deemed in compliance with paragraph (c)(2)(iii)(A) of this section if they are in compliance with § 92.8 of this subtitle." The Department informed the public of this interpretation in the proposed rule, and after reviewing public comments, the Department maintains the same position for essentially the same reason. Because this final rule repeals the taglines requirements of the 2016 Rule at § 92.8, entities will not be out of compliance with those requirements, and therefore they will satisfy the condition of the sentence quoted above from 45 CFR 155.205(c)(2)(iii)(A) that they not be out of compliance with taglines requirements in 45 CFR part 92. Although the Department did not propose conforming amendments to those two regulations, and therefore cannot finalize such amendments in this final rule, the Department will consider making appropriate changes to other regulations in the future.

Comment: Commenters, including a health insurance issuer, noted that the 2016 Rule's preamble vaguely defined "significant communications" to include "not only documents intended for the public . . . but also written notices to an individual, such as those pertaining to rights or benefits." 81 FR 31402. These commenters argued that because almost all written communications would be considered "significant" under this definition, most covered entities included a one- to two-page addition containing the nondiscrimination notice and taglines with most written communications. One health insurance issuer estimated

sending the notice and taglines approximately 15 million times in 2018, or about five times for every individual served. One commenter stated that because the Department determined that the notice and taglines requirement in the 2016 Rule imposes a significant financial burden on covered entities, the Department is within its authority to rescind it, especially because of an executive order that limits the effectiveness of subregulatory guidance. Others requested that the Department issue further guidance on what constitutes "significant" documents and communications, instead of removing the 2016 Rule's notice and taglines provisions.

Response: The Department agrees with comments that stated the 2016 Rule's notice and taglines requirements were imprecise and overly burdensome. The Department declines to retain those requirements while merely issuing more guidance on what constitute significant communications. First, the requirements are not mandated by statute, and although the 2016 Rule is a regulation and not subregulatory guidance, the Department has determined that its financial burden on covered entities was not justified by the protections or benefits it provided to LEP individuals. Second, the Department believes that other protections as finalized in this rule (and discussed below) better serve the language access needs of LEP individuals and, therefore, are more appropriate. Repeal of the notice and taglines requirements in this rule does not repeal all other notice and taglines requirements that exist under other statutes and rules.

b. Discrimination on the Basis of Disability

The Department is committed under this final rule to enforce protections against discrimination on the basis of disability, both in specific provisions set forth in § 92.102–92.105, and as applicable through the underlying Section 504 regulations, which are more broadly applicable under Section 1557 of the ACA. Comments on these issues are discussed in the section below on Subpart B of the Section 1557 regulation.

c. Discrimination on the Basis of Age

Comment: Commenters expressed concerns that the changes in the proposed rule will lead to discriminatory practices in health plans. In the absence of explicit language prohibiting health plans from discriminating based on age as set forth in § 92.207 of the 2016 Rule, they alleged, health plans may unlawfully

⁶¹ See Title VI (45 CFR 80.6 and Appendix to Part 80), Section 504 (45 CFR 84.8), Title IX (45 CFR 86.9), and the Age Act (45 CFR 91.32).

⁶² 84 FR at 27881.

deny, cancel, or limit policies, deny or limit coverage for claims, impose additional cost-sharing on coverage, or use discriminatory marketing practices or benefit designs because of age. In particular, some commenters believe that health insurance plans will offer formularies and plan options that deny treatment for older individuals who generally have more health complications. For example, they say, this practice may already be in place with some health plans that offer coverage for hearing aids to children and youths but deny it to older adults. Some commenters said the proposed rule will lead to discrimination against older LGBT adults, who already have high levels of poverty and health disparities, and will contribute to worse health outcomes. Some commenters also alleged the proposed rule encourages unlawful discrimination against LGBT youth, who are already at increased risk of discrimination.

Response: This final rule retains clear language prohibiting discrimination on the basis of age, as defined in the Age Act and enforced through its implementing regulations, in any covered programs and activities, including health plan marketing and benefit design. Moreover, the ACA has specific provisions which limit the extent to which health plans offered under the ACA can charge higher premiums based on age, as well as specific provisions which require guaranteed issuance, address permissible cost sharing requirements, and establish standards for essential benefits and formularies.

The Department remains committed to vigorous enforcement of this prohibition on behalf of all Americans, including LGBT adults and youth. The Department declines to comment on specific cases outside of the normal enforcement process but encourages anyone who has experienced unlawful discrimination, including with respect to health plans, to file a complaint with OCR.

Comment: Commenters expressed concern that the proposed rule will lead to health plans using their benefit design to discriminate against individuals with chronic conditions who are more expensive to insure, including children and youth with serious health conditions. One commenter represented a 13 year old with Down syndrome who, the commenter said, was denied coverage by a private health insurer because that health insurer categorically denied coverage for individuals with Down syndrome.

Response: Many serious health conditions, including Down syndrome, qualify as disabilities under Section 504, which Section 1557 incorporates. The Department will enforce vigorously Section 1557's prohibition on discrimination on the basis of disability against all covered entities, including when discrimination is alleged to have taken place in benefit design. As finalized, the amended § 147.104 would prohibit health insurance issuers from employing "benefit designs that . . . discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, expected length of life, degree of medical dependency, quality of life, or other health conditions." The ACA also establishes requirements, applicable to health insurance issuers offering individual and group health insurance, concerning guaranteed issuance and renewal.⁶³ Concerns about whether private health insurers are covered entities are addressed below in the section on this rule's scope of application.

Comment: Some commenters contended the proposed rule will allow health plans to place age restrictions on certain medications, such as age restrictions on contraceptives for youth.

Response: To the extent that covered entities (including health plans) place restrictions based on age, OCR would assess on a case-by-case basis whether such restrictions violate Section 1557's incorporation of grounds prohibited under the Age Act. The Age Act does not forbid certain age distinctions in Federal, State, or local statutes and ordinances, or an action that reasonably takes age into account as a factor that is necessary to the normal operation or achievement of a statutory objective of a program.⁶⁴

d. Discrimination on the Basis of Sex i. Generally

Comment: Commenters offered different points of view on the definition of the term "sex," as this relates to the definition of discrimination "on the basis of sex."

A number of commenters stated that the Department had proposed a new definition of "sex" for the Section 1557 rule. Some objected that any reinterpretation of "sex" should be addressed by Congress or left to the courts, rather than administrative agencies. Others stated that the proposed regulations realign the Department's interpretation with several decades of Federal court decisions and

with the logical interpretation based on the statute's plain meaning of sex (namely sex in its biological meaning), which until 2017 had been the consistent consensus of the Federal courts.

Some commenters said that sex is a binary reality of male and female, and that Title IX and Section 1557 apply this historic understanding of sex. Some commenters stated that there is no evidence in the legislative history of either Title IX or the ACA that Congress intended to prohibit gender identity or sexual orientation discrimination in Section 1557, and that the purpose of Title IX is to ensure women (as biologically distinct from men) equal opportunities in Federally funded programs and activities.⁶⁵ Commenters said that the 2016 Rule exceeded the Department's authority by adopting a new, different, or expansive definition of prohibited sex discrimination in its Section 1557 regulation, although Congress declined to do so when presented with the opportunity and instead incorporated its meaning from Title IX which was passed in 1972. Some commenters noted that Congress has repeatedly considered adding gender identity and sexual orientation as protected categories in nondiscrimination laws related to education,⁶⁶ or to employment,⁶⁷ or in bills that would redefine discrimination "on the basis of sex"⁶⁸ as the 2016 Rule attempted, but that Congress has chosen not to do so.⁶⁹ Where Congress has chosen to prohibit "gender identity" discrimination in other statutes, it added the term "gender identity" as a

⁶⁵ Commenters cited 118 Cong. Rec. 5808 (1972); 44 FR at 71423.

⁶⁶ See, e.g., *Student Non-Discrimination Act of 2018*, H.R. 5374, 115th Congress, 2nd sess.; online at: <https://www.congress.gov/115/bills/hr5374/BILLS-115hr5374ih.pdf>; "No student shall, on the basis of actual or perceived sexual orientation or gender identity . . . be excluded from participation in, or be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance."

⁶⁷ See, e.g., *Employment Non-Discrimination Act of 2013*, S. 815, 113th Congress, 1st sess.; online at: <https://www.govtrack.us/congress/bills/113/s815/text>; "It shall be an unlawful employment practice for an employer—(1) to fail or refuse to hire or to discharge any individual, or otherwise discriminate against any individual . . . because of such individual's actual or perceived sexual orientation or gender identity . . ."

⁶⁸ See, e.g., *Equality Act*, H.R. 5, 116th Congress, 1st sess.; online at: <https://www.congress.gov/116/bills/hr5/BILLS-116hr5rfs.pdf>; amends *Civil Rights Act of 1964* "by striking 'sex,' each place it appears and inserting 'sex (including sexual orientation and gender identity)' . . ."

⁶⁹ See H.R. 1652, 113th Cong. (2013); S. 439, 114th Cong. (2015); H.R. 3185, 114th Cong. (2015); S. 1858, 114th Cong. (2015); H.R. 2015, 110th Cong. (2007); H.R. 2981, 111th Cong. (2009); S. 811, 112th Cong. (2011); See H.R. 4636, 103rd Cong. (1994).

⁶³ See 42 U.S.C. 300gg–1, 300gg.2.

⁶⁴ 45 CFR 90.14, 90.15.

new and separate category of prohibited grounds in addition to “sex” without redefining “sex” itself.⁷⁰ Other commenters said that reliance on legislative history is an improper method of statutory interpretation, and that the Supreme Court has deemed reliance on Congressional inaction to be inappropriate.

One commenter cited U.S. Supreme Court cases as setting forth the binding legal standard of sex discrimination as a binary biological concept. The commenter cited *Tuan Anh Nguyen v. I.N.S.* as rejecting an approach of “[m]echanistic classification of all our differences as stereotypes” because it obscures the reality that “physical differences between men and women . . . are enduring.” 533 U.S. 53, 73 (2001), as well as Justice Ginsburg’s majority opinion in *United States v. Virginia*, which held that “[T]he two sexes are not fungible; a community made up exclusively of one [sex] is different from a community composed of both.” 518 U.S. at 533 (1996).

Some commenters stated that changing cultural preferences should not be the standard for interpreting legal texts. Others analogized Title IX’s lack of a definition of “sex” to the lack of a definition of “race” under the Civil Rights Act of 1964, where courts looked to the plain and ordinary meaning to interpret it as based on a person’s “family, tribe, people, or nation belonging to the same stock.” Other commenters cited analyses of public meanings at the time of adoption, concluding that when “gender” was used, which was rare, it was used in contrast to sex: Gender referred to socially constructed roles, while sex, according to virtually every dictionary of the time, referred to biological differences between men and women.⁷¹ Other commenters stated that use of the term “gender” (with regard to one’s identity) as separate from “sex” (with regard to one’s biology) is relatively new and is improperly interpreted today as evidence of support for gender-identity legal theories in prior legal precedents or decades-old statutes. Some commenters asserted that at the time of the passage of the underlying Federal civil rights statutes, “sex” and “gender” were commonly used identically under

Title VII, Title IX, and the Equal Protection Clause to refer to biological sex.⁷² However, other commenters disagreed, and stated that historical sources demonstrate the variability and complexity of the concept of sex to include “[t]he sum of the morphological, physiological, and behavioral peculiarities of living beings.”

Some commenters stated that the terms male or female apply to everyone. Commenters stated that the “sex” of an organism is a clear, provable, objective, identifiable, biological, and binary reality according to relevant textbooks, studies, and articles from various specialties in the scientific community, including embryology, genomics, psychiatry, clinical anatomy, neuropsychology, developmental biology, genetics, endocrinology, neuropsychiatry, radiology, organismic and evolutionary biology, neuropharmacology, pediatrics, and pathology.⁷³ Healthcare providers stated that the reality of sex, as male or female, can be identified through advanced chromosomal testing such as karyotyping or simple genital identification at birth in roughly 99.98% of cases, leaving the remaining 0.02% as diagnoses with intersex or ambiguous conditions. Others stated that

delineating a binary division on the basis of reproductive organs reflected an outdated paradigm and was not universally descriptive of transgender, transitioning, androgynous, intersex, two-spirit, or questioning individuals.

Some commenters stated that removal of a regulatory definition of “sex” leaves the regulation ambiguous, and the 2016 Rule was justified in clarifying by adding a definition that included gender identity and termination of pregnancy. Other commenters stated that the public widely understands the state of being either male or female, as determined by one’s chromosomes or genetics, which leaves no ambiguity.

Response: Because Section 1557 incorporates Title IX’s prohibition on discrimination “on the basis of sex,” it presupposes that the executive and judicial branches can recognize the meaning of the term “sex.” This final rule repeals the 2016 Rule’s definition of “on the basis of sex,” but declines to replace it with a new regulatory definition. See 84 FR at 27857. Instead, the final rule reverts to, and relies upon, the plain meaning of the term in the statute.

“Sex” according to its original and ordinary public meaning refers to the biological binary of male and female that human beings share with other mammals. As noted in briefs recently submitted by the Federal government to the Supreme Court, discrimination on the basis of sex means discrimination on the basis of the fact that an individual is biologically male or female.⁷⁴ Several commenters reference various sources of legislative history: That of Title IX, of Congress’s decision to add protections on the basis of sexual orientation and gender identity to other statutes alongside protections on the basis of sex, and of Congress’s repeated refusal to add those protections in other cases.⁷⁵ These sources support the plain

⁷² See *Glenn v. Brumby*, 663 F.3d 1312, 1315 (11th Cir. 2011) (citing *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 440–41 (1985)). (“In describing generally the contours of the Equal Protection Clause, the Supreme Court noted its application to this issue, referencing both gender and sex, using the terms interchangeably . . .”).

⁷³ Commenters cited texts including, e.g., T.W. Sadler, Ph.D., *Langman’s Medical Embryology* (Philadelphia: Lippincott Williams & Wilkins, 2004), 40; William J. Larsen, Ph.D., *Human Embryology* (New York: Churchill Livingstone, 2001), 519; Keith L. Moore, Ph.D., D.Sc., and T.V.N. Persaud, M.D., Ph.D. D.Sc. FRCPath., *The Developing Human: Clinically Oriented Embryology* (Philadelphia: Saunders/Elsevier, 2003), 35; Maureen L. Condic, Ph.D. and Samuel B. Condic, Ph.D., “Defining Organisms by Organization,” *National Catholic Bioethics Quarterly* 5, no. 2 (Summer 2005): 336; Lawrence S. Mayer, Ph.D., and Paul R. McHugh, M.D., “Sexuality and Gender Findings from the Biological, Psychological, and Social Sciences,” *New Atlantis* 50 (Fall 2016): 89; Scott F. Gilbert, Ph.D. *Developmental Biology* (Sunderland, Mass.: Sinauer Associates, 2016), 519–20; and William J. Larsen, Ph.D., *Human Embryology* (New York: Churchill Livingstone, 2001), 307; Nichole Rigby, M.A. and Rob J. Kulathinal, Ph.D., “Genetic architecture of sexual dimorphism in humans,” *J. of Cellular Physiology* 230, no. 10 (2015): 2305; Jonathan C.K. Wells, Ph.D., “Sexual dimorphism of body composition,” *Best Practice & Research: Clinical Endocrinology & Metabolism* 21 (2007): 415; Larry Cahill, Ph.D., “His Brain, Her Brain,” *Scientific American*, October 1, 2012; Larry Cahill, Ph.D. “A Half-Truth Is a Whole Lie: On the Necessity of Investigating Sex Influences on the Brain,” *Endocrinology* 153 (2012): 2542; Madhura Ingalhalikar, Ph.D., et al., “Sex differences in the structural connectome of the human brain,” *Proceedings of the National Academy of Sciences* 111 (January 2014): 823–28.

⁷⁰ 18 U.S.C. 249(a)(2).

⁷¹ Commenters cited Joanne Meyerowitz, A History of “Gender,” 113 a.m. Hist. Rev. 1346, 1353 (2008); David Haig, *The Inexorable Rise of Gender and the Decline of Sex: Social Change in Academic Titles, Archives of Sexual Behavior* 1945–2001 (Apr. 2004); Sari L. Reisner, et al., “Counting” Transgender and Gender-Nonconforming Adults in Health Research, *Transgender Studies Quarterly* 37 (Feb. 2015); New Oxford Am. Dictionary 721–22, 1600 (3d ed. 2010).

⁷⁴ *Bostock v. Clayton Cty. Bd. of Commissioners*, 2019 WL 4014070 at *25 (U.S. 2019) (Brief for the United States as *Amicus Curiae* Supporting Affirmance in No. 17–1618 (*Bostock v. Clayton Cty. Bd. of Commissioners*) and Reversal in No. 17–1623 (*Altitude Express Inc. v. Zarda*)); Statement of Interest for DOJ, *Soule v. Conn. Ass’n of Schools*, 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 4–5 (“When Congress enacted Title IX in 1972, the ‘ordinary, contemporary, common meaning’ of ‘sex’ was biological sex. . . . Title IX consistently uses ‘sex’ as a binary concept capturing only two categories: Male and female.”).

⁷⁵ Examples of bills where Congress chose not to enact prohibitions on discrimination on the basis of sexual orientation or gender identity include: The Employment Non-Discrimination Act (ENDA), which has been introduced ten times in the U.S. House of Representatives but has never proceeded out of committee: H.R. 4636 (103rd Cong. 1994); H.R. 1863 (104th Cong. 1995); H.R. 1858 (105th Cong. 1997); H.R. 2355 (106th Cong. 1999); H.R. 2692 (107th Cong. 2001); H.R. 3285 (108th Cong.

meaning of Title IX, but are not the only source of support for the Department's understanding of the meaning of the word "sex." Contemporaneous dictionaries and common usage make clear that "sex" in Title IX means biological sex.⁷⁶ Even today, the article on gender dysphoria in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition defines "sex" to "refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and nonambiguous internal and external genitalia."⁷⁷ The term "gender" may sometimes be ambiguous. However, neither Title IX nor Section 1557 uses that term, and the ordinary public meaning of the term "sex" in Title IX is unambiguous. In order to avoid ambiguities associated with the term "gender," the Department's regulations and guidance have, where relevant, distinguished sex (in its biological meaning) from gender, gender identity, or gender expression.⁷⁸

2003); H.R. 2015 (110th Cong. 2007); H.R. 2981 (111th Cong. 2009); H.R. 1397 (112th Cong. 2011); H.R. 1755 (113th Cong. 2013). Similarly, the Equality Act has been introduced in three successive sessions of Congress; it did not proceed out of committee in the 114th and 115th Congresses, and it passed the House of Representatives on May 17, 2019. See H.R. 3185 (114th Cong. 2015); S. 1828 (114th Cong. 2015); H.R. 2282 (115th Cong. 2017); S. 1006 (115th Cong. 2017); H.R. 5 (116th Cong.) (introduced Mar. 3, 2019).

⁷⁶ See New Oxford Am. Dictionary 721–22, 1600 (3d ed. 2010). Some Federal courts have gone farther, using the legislative history to show that "Congress never considered nor intended" for sex under Title VII (which is often used to interpret Title IX) to apply to "anything other than the traditional concept of sex," and that coverage for a concept such as transgender status "surely" would have been mentioned in the legislative history had Congress intended such an "all-encompassing interpretation." The Department finds the analysis in these Court decisions persuasive, but declines to rely on their reasoning. See *Ulane v. Eastern Airlines Inc.*, 742 F. 2d 1081, 1085 (7th Cir. 1984) (analyzing "The total lack of legislative history supporting the sex amendment coupled with the circumstances of the amendment's adoption"); see also *Voyles v. Ralph K. Davies Medical Center*, 403 F. Supp. 456, 457 (N.D. Cal. 1975), *aff'd*, 570 F.2d 354 (9th Cir. 1978) (finding a "void" in the legislative history and concluding that Congress's "paramount, if not sole, purpose in banning employment practices predicated upon an individual's sex was to prohibit conduct which, had the victim been a member of the opposite sex, would not have otherwise occurred. Situations involving transsexuals, homosexuals or bi-sexuals were simply not considered.").

⁷⁷ American Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders*, 5th ed. (Arlington, VA: American Psychiatric Ass'n, 2013), 451–59.

⁷⁸ See 45 CFR 411.5; also 79 FR 77771, 84 FR 27854. See NIH, Office of Research on Women's Health, "Sex & Gender," <https://orwh.od.nih.gov/sex-gender/> ("NIH is committed to improving health by supporting the rigorous science that drives medical advances. Sex/gender influence health and

Some commenters challenge the Department's approach by pointing to medical conditions that they refer to as "intersex." The term refers to rare medical conditions that the medical literature, since 2006, has preferred to call "disorders of sexual development" (DSD).⁷⁹ DSD are estimated to be present in 0.0167%–0.022% of the population. More importantly, DSD are "congenital conditions in which development of chromosomal, gonadal, or anatomic sex is atypical."⁸⁰ This medical definition refers to, and presupposes, the ordinary biological and binary meaning of "sex," just as the definition of any medical disorder presupposes an understanding of healthy baseline functionality.

Title IX,⁸¹ along with its implementing regulations,⁸²

disease, and considering these factors in research informs the development of prevention strategies and treatment interventions for both men and women. 'Sex' refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. 'Gender' refers to socially constructed and enacted roles and behaviors which occur in a historical and cultural context and vary across societies and over time. . . . With continuous interaction between sex and gender, health is determined by both biology and the expression of gender.").

For these reasons, in general throughout this document the Department prefers to use simply the term "sex" because the plain, ordinary meaning of "sex" is already biological, so it is generally redundant to use the term "biological sex." Where the Department uses the term "biological sex," or similarly "biological male" or "biological female," it does so merely to emphasize this point and for the purposes of clarity in particular contexts, and not to imply that there is a distinction between biological sex and sex under the plain meaning of the term.

⁷⁹ R.L.P. Romao, J.L. Pippi Salle, and D.K. Wherett, "Update on the Management of Disorders of Sex Development," *Pediatric Clinics of North America* 59 (2012), 853–69; I.A. Hughes, "Disorders of Sex Development: A New Definition and Classification," *Best Practice & Research Clinical Endocrinology & Metabolism* 22:1 (2008), 119–34.

⁸⁰ A. Rawal and P. Austin, "Concepts and Updates in the Evaluation and Diagnosis of Common Disorders of Sexual Development," *Current Urology Reports* 16:83 (2015), 1–9; I. Hughes et al., "Consequences of the ESPE/LWPES guidelines for diagnosis and treatment of disorders of sex development," *Best Practice & Research Clinical Endocrinology & Metabolism* 21:3 (2007), 351–65; P.A. Lee et al., "Consensus Statement on Management of Intersex Disorders," *Pediatrics* 118:2 (2006), e488–500.

⁸¹ See 42 U.S.C. 1681(a)(2) ("both sexes"), (a)(2) ("one sex" and "other sex"), (a)(6)(B) ("Men's" and "Women's"), (a)(6)(B) ("Boy" and "Girl"); (a)(7)(A) ("Boys" and "Girls"), (a)(7)(B)(i) ("Boys" and "Girls"), (a)(8) ("father-son" "mother-daughter"), and (a)(8) ("one sex" and "other sex"). See also 42 U.S.C. 1681(a)(2)(6) ("fraternity" and "sorority").

⁸² See language such as "male and female," "both sexes," "each sex," "one sex . . . the other sex," and "boys" and "girls," at 45 CFR 86.2(s), 86.7, 86.17(b)(2), 86.21(c)(4), 86.31(c), 86.32(b)(2) and (c)(2), 86.33, 86.37(a)(3), 86.41(b) and (c), 86.55(a), 86.58(a) and (b), 86.60(b), and 86.61. See similarly Department of Education Title IX regulation at 34

consistently understands "sex" to refer to the biological binary categories of male and female only.⁸³ The Department of Justice has recently noted that "[i]f the term 'sex' in Title IX included 'gender identity'—which, according to the American Psychiatric Association, may include 'an individual's identification as . . . some category other than male or female,'" *Diagnostic and Statistical Manual of Mental Disorders Fifth Edition* 451 (2013) (emphasis added)—then multiple Title IX provisions would make little sense."⁸⁴ Many comments on the 2019 NPRM assume that Section 1557's protection against discrimination "on the basis of sex" covers women's health issues including pregnancy, uterine cancer, and prenatal and postpartum

CFR 106.2(s), 106.7, 106.17(b)(2), 106.21(c)(4), 106.31(c), 106.32(b)(2) and (c)(2), 106.33, 106.37(a)(3), 106.41(b) and (c), 106.55(a), 106.58(a) and (b), 106.60(b), and 106.61; Department of Justice Title IX regulation at 28 CFR 54.105, 54.130, 54.230(b)(2), 54.235(b)(3), 54.300(c)(4), 54.400(c), 54.405(b)(2) and (c)(2), 54.410, 54.430(a)(3), 54.450(b) and (c)(2), 54.520(a), 54.535(a) and (b), 54.545(b), and 54.550. See also DOJ Coordination and Compliance Division, Title IX Regulations by Agency, https://www.justice.gov/crt/fcs/Agency_Regulations#2.

⁸³ Federal courts have also made this observation. See, e.g., *Doe v. Boyertown Area Sch. Dist.*, 897 F.3d 518, 522 (3d Cir. 2018) ("'Sex' is defined as 'the anatomical and physiological processes that lead to or denote male or female.' Typically, sex is determined at birth based on the appearance of external genitalia."); *Hively v. Ivy Tech Cmty. Coll.*, 853 F.3d 339, 362 (7th Cir. 2017) ("[i]n common, ordinary usage in 1964—and now, for that matter—the word 'sex' means biologically male or female.") (Sykes, J., dissenting) (emphasis in original); cf. *id.* at 357 ("we, who are judges rather than members of Congress, are imposing on a half-century-old statute a meaning of 'sex discrimination' [to include sexual orientation] that the Congress that enacted it would not have accepted.") (Posner, J., concurring); *G.G. ex rel Grimm v. Gloucester Cnty. Sch. Bd.*, 822 F.3d 709, 736 (4th Cir. 2016) ("Title IX was enacted in 1972 and the regulations were promulgated in 1975 and readopted in 1980, and during that time period, virtually every dictionary definition of 'sex' referred to the physiological distinctions between males and females, particularly with respect to their reproductive functions.") (Niemeyer, J., dissenting); Statement of Interest for DOJ, *Soule v. Connecticut Association of Schools*, 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 5 ("Other provisions of Title IX employ 'sex' as a binary term, and thus provide further confirmation that the prohibition on 'sex' discrimination does not extend to discrimination on the basis of transgender status or gender identity."); *Franciscan All, Inc. v. Burwell*, 227 F. Supp. 3d 660, 687 (N.D. Tex. 2016) ("the meaning of sex unambiguously refers to the biological and anatomical differences between male and female students as determined at their birth," quoting *Texas v. United States*, 201 F. Supp. 3d 810, 833 (N.D. Tex. 2016)); *Johnston v. Univ. of Pittsburgh of Commw. Sys. of Higher Educ.*, 97 F. Supp. 3d 657, 676 (W.D. Pa. 2015) ("[o]n a plain reading of the statute, the term 'on the basis of sex' in Title IX means nothing more than male and female, under the traditional binary conception of sex consistent with one's birth or biological sex").

⁸⁴ Statement of Interest for DOJ, *Soule v. Conn. Ass'n of Schools*, 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 5.

services. That assumption is correct: These issues are protected under Section 1557 because of the ordinary and biological meaning of “sex.”

Prior to the ACA, OCR itself had always applied Title IX in its enforcement actions using the biological binary meaning of sex.⁸⁵ Recently, OCR has resolved a number of Section 1557/ Title IX cases of discrimination against women in healthcare programs and activities funded by the Department, again relying on a biological understanding of sex.⁸⁶ The 2016 Rule itself presupposed the biological meaning of sex when it permitted “sex-specific” health programs that are “restricted to members of one sex,” when it incorporated “termination of pregnancy” into discrimination on the basis of sex, and when it referred repeatedly to “sex assigned at birth.”⁸⁷

Supreme Court case law on Title IX has consistently presupposed the biological and binary meaning of “sex.”⁸⁸ Even when some lower courts have recently extended Title VII or Title IX protections “on the basis of sex” to encompass gender identity, they have done so only by presupposing the ordinary public meaning of “sex” as a biological binary reality. In *Whitaker v. Kenosha Unified Sch. Dist.*, for example, the Seventh Circuit stated: “Here, the School District’s policy cannot be stated without referencing sex, as the School

District decides which bathroom a student may use based upon the sex listed on the student’s birth certificate. This policy is inherently based upon a sex-classification and heightened review applies.”⁸⁹ Likewise, in *Harris Funeral Homes*, the Sixth Circuit stated: “Here, we ask whether Stephens would have been fired if Stephens had been a woman who sought to comply with the women’s dress code. The answer quite obviously is no. This, in and of itself, confirms that Stephens’s sex impermissibly affected Rost’s decision to fire Stephens.”⁹⁰ In other words, Stephens “quite obviously” is not “a woman” because “Stephens’s sex” is male.⁹¹

The Department does not deny that some courts have caused confusion as to the meaning of sex in civil rights law. Conflicting views in the lower courts, however, do not preclude the Department, consistent with the position of the U.S. government, as set forth in briefs filed in the Supreme Court, from returning to its decades-long practice of conforming to the original and ordinary public meaning of “sex” in Title IX, a meaning that continues to be presupposed even in the same rulings that have caused this confusion.

Some lower courts have recently held that discrimination “on the basis of sex” encompasses gender identity or sexual orientation even when “sex” is understood in its ordinary, biological, and binary sense. These views will be addressed below in the relevant subsections.

Comment: Some commenters argued that the proposed rule would be

inconsistent with the purposes of the ACA; that the weight of law recognizes sexual orientation and gender identity as forms of sex discrimination; and that the proposed rule would undermine Congress’s intent to expand access to healthcare and healthcare coverage. Commenters emphasized that it is unacceptable for a healthcare facility to deny medical care to a patient based on the patient’s sexual orientation or transgender status.

Response: The Department does not condone the unjustified denial of needed medical care to anyone, and believes that everyone, regardless of gender identity or sexual orientation, should be treated with dignity and respect. The Department must interpret Congress’s purpose in passing the ACA by reading that statute’s plain text. The ACA sought to expand access to healthcare and healthcare coverage through some means but not others: in particular, Congress saw fit to incorporate into the ACA certain nondiscrimination protections, and not others. For example, in the unlikely event that a healthcare provider were to deny services to someone based solely on his or her political affiliation, the Department would not be able to address such denial of care under Section 1557. Under this final rule, OCR is committed to no less than full enforcement of the prohibitions on discrimination that Congress included in Section 1557, without exceeding the statutory text. Unlike other bases of discrimination, the categories of gender identity and sexual orientation (as well as political affiliation) are not set forth in those statutes.⁹²

Comment: Some insurers stated that they already took steps to come into compliance with prohibitions related to gender identity and termination of pregnancy in their plans under the 2016 Rule, and that they will incur burdens to change their plans. Other commenters stated that the 2016 Rule created burdens that, if unrelieved, would encumber their day-to-day affairs and limit their ability to provide healthcare services for their patients or healthcare coverage for their employees.

Response: As discussed in the Regulatory Impact Analysis below, this rule removes certain requirements, without requiring providers to incur new burdens related to those requirements. Whether or not the Department revises the regulation, the past expenditures incurred by insurers and other commenters to come into

⁸⁵ In the 2015 NPRM, the earliest record of the Department’s new understanding of sex discrimination cited was an OCR letter dated 12 July 2012. 80 FR 54176.

⁸⁶ U.S. Department of Health and Human Services, “HHS Office for Civil Rights Enters Into Agreement with Oklahoma Nursing Home to Protect Patients with HIV/AIDS from Discrimination” (2018), <https://www.hhs.gov/about/news/2017/09/08/hhs-office-for-civil-rights-enters-into-agreement-with-oklahoma-nursing-home.html>; “OCR works with DOJ to ensure Federally funded medical center provides communication services for deaf and hard of hearing patients” (2018), <https://www.hhs.gov/about/news/2017/12/20/ocr-works-with-doj-to-ensure-federally-funded-medical-center-provides-communication-services-for-deaf-and-hard-of-hearing-patients.html>; “HHS OCR Secures Agreement with MSU to Resolve Investigation into Sexual Abuse by Larry Nassar” (2019), <https://www.hhs.gov/about/news/2019/08/12/hhs-ocr-secures-agreement-msu-resolve-investigation-sexual-abuse-larry-nassar.html> (requiring chaperone policies where patients can request a chaperone of the same sex, meaning biological sex, during sensitive physical examinations).

⁸⁷ See 81 FR 31384, 31387, 31406, 31408–09, 31428, 31429, 31435, 31436, 31467, 31470, 31471, 31472.

⁸⁸ See, e.g., *Nat’l Collegiate Athletic Ass’n v. Smith*, 525 U.S. 459, 464 (1999) (Title IX claim based on allegation “that the NCAA discriminates on the basis of sex by granting more waivers from eligibility restrictions to male than female postgraduate student-athletes”); *Cannon v. Univ. of Chicago*, 441 U.S. 677, 680 (1979) (Title IX claim based on allegation that plaintiff’s “applications for admission to medical school were denied . . . because she is a woman”).

⁸⁹ 858 F.3d 1034, 1051 (7th Cir. 2017).

⁹⁰ *Equal Emp’t Opportunity Comm’n v. R.G. & G.R. Harris Funeral Homes*, 884 F.3d 560 (6th Cir. 2018), 575. See also certain passages during oral argument on appeal at the U.S. Supreme Court, e.g.: “here, Ms. Stephens, was being treated differently because of her sex. . . . Yes, if she had not been a—if she had not been assigned at birth the sex that she was assigned at birth, she would have been treated differently” (Kagan, J., Transcript of Oral Argument at 41, *R.G. & G.R. Harris Funeral Homes, Inc. v. E.E.O.C.*, 139 S. Ct. 1599 (2019) (No. 18–107), https://www.supremecourt.gov/oral_arguments/argument_transcripts/2019/18-107_4gcj.pdf); See also Mr. Cole, counsel for respondents at oral argument, *Id.* at 4–5: “None of [our] arguments ask this Court to redefine or, in Judge Posner’s words, update sex. They assume, arguing, that sex means at a minimum sex assigned at birth based on visible anatomy or biological sex.” *Id.* at 28: “[O]ur argument rests on text meaning, at a minimum, sex assigned at birth or biological sex, and everybody agrees— . . . [we are] asking you to interpret the statute as it is written and as everybody agrees it applies to sex assigned at birth.”

⁹¹ *Harris* 884 F.3d at 575. It is true that the *Harris* court referred to Stephens with female pronouns throughout the rest of its ruling, but it appeared to do so based on its concept of gender identity, not of sex. Had the *Harris* court employed female pronouns in the quoted passage, it would have visibly undermined the basis of its Title IX analysis.

⁹² The Department responds below to comments with respect to sexual orientation and gender identity specifically.

compliance with the 2016 Rule are “sunk costs” that cannot be recovered. With the finalization of this rule, insurers have the option—as they have had since December 31, 2016—of providing such coverage or not. Presumably some insurers will maintain coverage consistent with the 2016 Rule’s requirements and some will not. The final rule also does not alter the status quo, and thus does not impose burdens in this regard, because, independent of the finalization of this rule, the 2016 Rule’s provisions on gender identity and termination of pregnancy have been vacated by a final order and decision of a federal court.

Comment: Commenters expressed concern that the proposed rule would result in lack of information about gender transition-related services or termination of pregnancy, leaving patients without information about different surgical procedures and prescription options, and in danger of harm. Some argued that women, members of the LGBT community, people with disabilities, people with LEP, and racial minorities need additional specific protections because they will face greater burdens accessing healthcare due to “intersectionality” theories. Others, however, said it was not appropriate or reflective of current civil rights law to analogize sexual orientation or gender identity to race or other protected categories.

Some commenters argued that the 2016 Rule had decreased LGBT patients’ fears of discrimination, that the proposed rule will lead to discrimination against them (including by States, providers, marketplaces, agents, and brokers), and that this will increase their health disparities, mainly via poorer quality of care, lack of access to willing providers especially in rural areas, postponed care including preventive care, increased healthcare and insurance costs, and impediments to HIV patients’ access to medication. Commenters said the rule would undermine the President’s goal of eradicating HIV. Commenters relied on national and statewide reports and studies highlighting harm faced by LGBT people due to inadequate healthcare, including an increase in substance abuse; worsening psychiatric disorders; untreated depression leading to suicide; and higher rates of AIDS, HIV and other STIs, cancer, and behavioral health issues. These commenters also argued the proposed rule would permit LGBT people to suffer discrimination and hence stigmatic injury, which could also deter them from disclosing their LGBT status to their physicians and seeking proper

care. Commenters alleged high rates of mental conditions (e.g., depression),⁹³ behavioral conditions (e.g., substance use disorder),⁹⁴ developmental conditions (e.g., autism, learning disabilities), and physical conditions (e.g., HIV, heart disease) among the LGBT population. Commenters also expressed concerns about lack of communication and consent between providers and patients, and alleged that the risk of discrimination is heightened in vulnerable populations, including persons with developmental disabilities, persons with LEP, elderly patients with diminished capacity, and those who rely on surrogates or guardians for making medical decisions on their behalf. Others stated that OCR does not have authority to protect all forms of discrimination that may negatively impact people, but that it must act within its statutory authority.

Response: The Department is concerned with the health of all Americans. It acts to the fullest extent of its statutory authority in its efforts to improve the health and wellbeing of all. Under its civil rights authority, it enforces Federal laws requiring nondiscrimination on specified grounds, which in the case of Section 1557 are race, color, national origin, sex, age, and disability. When OCR receives a claim alleging multiple grounds of prohibited discrimination, the Department analyzes the elements of each claim according to the statute applicable to that ground.

Consistent with the text of the ACA and, in this case, the underlying civil rights statutes incorporated into the ACA, the Department seeks, wherever possible, to remove barriers to healthcare. Those barriers include regulations that impede providers’ ability to offer healthcare by interfering with their conscientious medical judgments or imposing unnecessary cost burdens on them. By removing such provisions from the 2016 Rule, the Department hopes to increase the availability of healthcare to all populations.

As a matter of policy, the Department recognizes and works to address barriers

to treatment caused by stigma about depression, anxiety, substance use disorder, and other comorbid mental and behavioral health conditions.⁹⁵ With regard to HIV, this final rule does not alter or affect the longstanding Federal protections against discrimination for individuals with HIV: Section 504, and hence also this final rule, prohibits discrimination on the basis that an individual has HIV.⁹⁶ OCR continues to pursue major enforcement actions under its authorities⁹⁷ and to provide the public guidance⁹⁸ to protect the rights of persons with HIV or AIDS. HHS remains committed to ensuring that those living with HIV or AIDS receive full protection under the law, in accordance with full implementation of the President’s National HIV/AIDS Strategy.⁹⁹

Regarding commenters’ worries about informed consent, this final rule does not repeal any informed consent requirements. Besides many relevant State laws,¹⁰⁰ CMS regulations also

⁹⁵ See, e.g., Pain Management Task Force, “Pain Management Best Practices, Fact Sheet on Stigma” (Aug. 13, 2019), https://www.hhs.gov/sites/default/files/pmtf-fact-sheet-stigma_508-2019-08-13.pdf (“Compassionate, empathetic care centered on a patient-clinician relationship is necessary to counter the suffering of patients . . . Patients with painful conditions and comorbidities, such as anxiety, depression or substance use disorder (SUD) face additional barriers to treatment because of stigma.”).

⁹⁶ See 29 U.S.C. 705(20) (incorporating ADA definition of disability into Section 504); 42 U.S.C. 12102(1)–(3); 28 CFR 35.108(d)(2)(iii)(I).

⁹⁷ See, e.g., “HHS Office for Civil Rights Secures Corrective Action and Ensures Florida Orthopedic Practice Protects Patients with HIV from Discrimination” (Oct. 30, 2019), <https://www.hhs.gov/about/news/2019/10/30/hhs-ocr-secures-corrective-action-and-ensures-fl-orthopedic-practice-protects-patients-with-hiv-from-discrimination.html>; “HHS Office for Civil Rights Enters Into Agreement with Oklahoma Nursing Home to Protect Patients with HIV/AIDS from Discrimination” (Sept. 8, 2017), <https://www.hhs.gov/about/news/2017/09/08/hhs-office-for-civil-rights-enters-into-agreement-with-oklahoma-nursing-home.html>.

⁹⁸ See OCR, “Know the Rights That Protect Individuals with HIV and AIDS,” <https://www.hhs.gov/sites/default/files/ocr/civilrights/resources/factsheets/hiv aids.pdf>; OCR, “Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS,” <https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html>.

⁹⁹ See “Ending the HIV Epidemic: A Plan for America,” <https://www.hiv.gov/Federal-response/ending-the-hiv-epidemic/overview>.

¹⁰⁰ See, e.g., Alaska Stat. § 09.55.556(a); Ark. Code Ann. § 16–114–206; Del. Code Ann. tit. 18, § 6852; Ga. Code Ann. § 31–9–6.1; Haw. Rev. Stat. § 671–3; Idaho Code Ann. § 39–4304; Ind. Code § 16–36–1.5–7; Ky. Rev. Stat. Ann. § 304.40–320; La. Rev. Stat. Ann. § 40:1299.40; Me. Rev. Stat. Ann. tit. 24 § 2905; Neb. Rev. Stat. § 44–2816; Nev. Rev. Stat. § 449.710; N.Y. Pub. Health Law § 2805–d; N.C. Gen. Stat. § 90–21.13; Or. Rev. Stat. § 677.097; 40 Pa. Cons. Stat. § 1303.504; Tenn. Code Ann. § 29–26–118; Tex. Rev. Civ. Stat. Ann. art. 4590i, § 6.02;

Continued

require, as a condition of participation in Medicare, that patients (or their legal surrogate) have the right to make informed decisions, the right to surgical informed consent policies,¹⁰¹ and the right to properly executed informed consent forms.¹⁰² Most States' malpractice laws address negligent failure to communicate risks and benefits of medical treatment options. Basic elements of informed consent with respect to participation in a clinical trial, for example, include: (1) Providing information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate.¹⁰³

The Department knows of no data showing that the proper enforcement of Federal nondiscrimination law according to statutory text will disproportionately burden individuals on the basis of sexual orientation and/or gender identity. Because the 2016 Rule explicitly declined to make sexual orientation a protected category, and because the Rule's gender identity provision has been legally inoperative since December 31, 2016, to the extent that LGBT individuals suffer future harms, it cannot be attributed to the Department's finalizing this rule, as opposed to other causes.

Comment: Commenters raised concerns that, without the 2016 Rule's provisions, certain insurers, such as those offering short-term limited duration insurance plans, would not offer coverage for conditions that affect only women, such as uterine cancer. Some commenters stated that the underlying Title IX regulatory provisions are insufficient by themselves to address access to insurance coverage of procedures provided to a single sex in healthcare. Some commenters stated that, without the 2016 Rule, women would not be able to afford insurance for medical and hospital care.

Response: The Department is strongly committed to promoting women's health. The Department enforces or implements ACA provisions that protect patient access to obstetrical and gynecological care.¹⁰⁴ The Department also enforces other provisions, both within and outside the ACA, that, for example, provide for maternity and

newborn care as essential health benefits,¹⁰⁵ require coverage of women's preventive health services,¹⁰⁶ establish (as a matter of statute) the HHS Office of Women's Health and the Pregnancy Assistance Fund,¹⁰⁷ and promote young women's breast health awareness.¹⁰⁸

The Department's commitment to women's health also includes vigorous enforcement of Section 1557's prohibition on sex-based discrimination. Under HHS's Title IX regulations, which OCR will use for enforcing Section 1557, covered entities must provide medical insurance benefits, services, policies, and plans without discrimination on the basis of sex. This does not preclude a covered entity's providing a covered benefit or service that is used uniquely by individuals of one sex or the other, such as uterine cancer treatments. However, any plan that includes full-coverage health insurance or services must encompass gynecological care.¹⁰⁹ As discussed in the relevant section below, the Department is bound by applicable law in determining the extent to which Section 1557 covers short-term limited duration insurance.

Comment: Some commenters said that the Department was wrong to claim in the 2019 NPRM that State and local entities are better equipped to address issues of gender dysphoria or sexual orientation, because they say that fifty percent of the LGBT population lives in States without laws prohibiting insurance companies from discriminating based on LGBT status. Others said that, because States like New York explicitly protect persons who identify as LGBT, the new rule will cause confusion for providers and patients about people's rights under Federal and State law. Some commenters suggested that including gender identity and sexual orientation in the Final Rule would reduce ambiguity in its interpretation and implementation.

Response: States and localities do indeed manifest a range of different views on what specific protections should be accorded to the categories of sexual orientation and gender identity in civil rights law, including healthcare civil rights law. That is precisely why, under our Constitutional Federal system, it is appropriate not to preempt States' diverse views on these topics without a clear mandate from Congress to do so. This final rule complies with

the federalism-related portions of Executive Orders 12866 and 13132 by avoiding undue interference with State, local, or tribal governments in the exercise of their governmental functions. It leaves them free to balance the multiple competing considerations involved in the contentious and fraught set of questions surrounding gender dysphoria and gender identity, and to adopt protections on the basis of sexual orientation or gender identity to the extent that they see fit (so long as they comply with Federal law).¹¹⁰

The Department notes, furthermore, that under the guaranteed issuance and renewal provisions of the ACA, health insurance issuers that offer health insurance coverage in the individual or group market in a state must accept every employer and every individual in that state that applies for such coverage, and must renew or continue in force such coverage at the option of the plan sponsor or the individual. *See* 42 U.S.C. 300gg-1 (guaranteed issuance), 300gg-2 (guaranteed renewability). Federal law similarly limits the bases on which a health insurance issuer can vary premium rates in the individual or small group market; such bases are limited to type of coverage (individual or family), rating area, age, and tobacco use. 42 U.S.C. 300gg. Thus, commenters' concern that LGBT individuals could be denied coverage if the Section 1557 rule does not include gender identity (or sexual orientation) is misplaced.

Comment: One commenter expressed concern that the proposed rule will have an effect beyond the United States by showing the international community that the United States Federal government does not recognize protections for individuals based on gender identity or sexual orientation in healthcare.

Response: The Department is not primarily responsible for the United States' foreign relations. Moreover, the Department has an obligation to implement the statutes according to the plain language of the text passed by Congress (unless unconstitutional), regardless of international implications.

Comment: Some commenters requested that the Department retain all guidance it had issued under the 2016 Rule. Other commenters stated that components of HHS continue to offer

Utah Code Ann. § 78-14-5; Vt. Stat. Ann. tit. 12, § 1909; Wash. Rev. Code Ann. § 7.70.050; Wis. Stat. Ann. § 448.30.

¹⁰¹ 42 CFR 482.51(b)(2).

¹⁰² 42 CFR 482.24(c)(4)(B)(v).

¹⁰³ 45 CFR 46.116-117 (HHS Office of Human Research Subject regulations).

¹⁰⁴ *See, e.g.*, 42 U.S.C. 300gg-19a(d).

¹⁰⁵ 42 U.S.C. 18022(b)(1)(D).

¹⁰⁶ 42 U.S.C. 300gg-13.

¹⁰⁷ 42 U.S.C. 237a; 42 U.S.C. 18202.

¹⁰⁸ 42 U.S.C. 280m.

¹⁰⁹ *See, e.g.*, 45 CFR 86.39.

¹¹⁰ Ambiguity in the 2016 Rule's provisions regarding gender identity is addressed below. The Department further notes that sexual orientation was explicitly rejected as a protected category under the 2016 Rule. 81 FR 31390 ("OCR has decided not to resolve in this rule whether discrimination on the basis of an individual's sexual orientation status alone is a form of sex discrimination.").

inconsistent guidance about the legal interpretation of the 2016 Rule.

Response: The Department stated in the preamble to the proposed rule that guidance under the 2016 Rule that conflicted with the proposed rule was suspended until further notice.¹¹¹ All such guidance is hereby withdrawn, effective upon publication of this final rule, and is in the process of being removed from the Department's website. Pursuant to Executive Order 13891, the Administration is also undertaking efforts to comprehensively review guidance documents "to ensure that Americans are subject to only those binding rules imposed through duly enacted statutes or through regulations lawfully promulgated under them, and that Americans have fair notice of their obligations,"¹¹² which also requires removal of inconsistent guidance from departmental websites.

ii. Gender Identity, Including Single-Sex Services Under § 92.206 of the 2016 Rule

The Department proposed to repeal the 2016 Rule's definition of "on the basis of sex" to encompass gender identity, which the 2016 Rule defined as "an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual's sex assigned at birth."¹¹³ The Department also proposed to repeal § 92.206 of the 2016 Rule, which has three elements. First, the section required covered entities not to discriminate "on the basis of sex" (as defined in § 92.4 of the 2016 Rule) in providing access to health programs and activities. Second, it required them to "treat individuals consistent with their gender identity." Third, it prohibited covered entities from "deny[ing] or limit[ing] health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to

which such health services are ordinarily or exclusively available."¹¹⁴

Comment: Commenters offered varying views on the state of gender-identity nondiscrimination protections under current Federal law. Some commenters alleged that it is settled law that Section 1557 prohibits gender identity discrimination. Others stated that, in other Federal court decisions on Title VII and Title IX, the text of the Title IX statute and regulation are held to be "at least susceptible to" the interpretation that it prohibits anti-transgender bias.¹¹⁵

Other commenters disagreed, stating that the courts are not unanimous on the question and pointed to legal precedent saying that gender identity is not encompassed by sex discrimination under Federal civil rights statutes. Commenters stated that the 2016 Rule had departed from existing civil rights law by creating new prohibited conduct unsupported by the text of the statutes. Commenters stated that Title IX has been interpreted by the courts for decades to apply to biological women.¹¹⁶ Other commenters stated that the fact that the Supreme Court has agreed to consider the legality of the general theory proposed in the 2016 Rule demonstrates it is a novel and contested legal issue.¹¹⁷ Other commenters stated Congress clearly intended "sex discrimination" to be defined with reference to biological classification as male or female, and that is the only understanding that is reasonably supported by the text, history, or structure of the relevant law. Some criticized the 2016 Rule's reliance on the EEOC's opinion in *Macy v. Holder*, 2012 EEO PUB LEXIS 1181, 112 FEOR (LRP) 257 (2012) (Title VII).

Response: The Department disagrees with commenters who contend that Section 1557 or Title IX encompass gender identity discrimination within their prohibition on sex discrimination. Some of the cases referenced by such commenters were decided under the Equal Protection Clause of the Constitution,¹¹⁸ under which courts have applied intermediate levels of scrutiny, permitting governments to adopt "discriminatory means" on the basis of sex only insofar as those means

are substantially related to the achievement of important governmental objectives and are not "used to create or perpetuate the legal, social, and economic inferiority of women."¹¹⁹ The Department does not agree that the Equal Protection cases cited by these commenters require Title IX to include a prohibition on gender identity discrimination. Unlike the Equal Protection Clause, Title VII and Title IX broadly forbid covered entities from discriminating on the basis of sex, with limited exemptions expressly provided in statute. Title VII exempts covered entities from the prohibition on sex discrimination where sex is a "bona fide occupational qualification."¹²⁰ Title IX exempts covered entities from the prohibition on sex discrimination for admissions to historically single-sex colleges, school father-son and mother-daughter activities (so long as reasonably comparable activities are provided for students of both sexes), beauty pageants, certain boys' or girls' conferences, single-sex voluntary youth service organizations, fraternities and sororities, and military training programs.¹²¹

The text of Title IX also demonstrates that it is not susceptible to an interpretation under which it would prohibit gender identity discrimination. The statute permits covered entities to maintain "separate living facilities for the different sexes," and it expressly presents this, not as an exemption from the nondiscrimination requirements, but as an "interpretation" of them: Separate-sex living facilities are not, as such, discriminatory.¹²² The Department's Title IX regulations likewise permit separate-sex housing, intimate facilities, physical education and human sexuality courses, and contact sports.¹²³ The statute presents these distinctions as being fully compatible with its nondiscrimination requirement. Nondiscrimination requires that separate-sex facilities and programs be (where relevant) comparable to one another, but the existence of separate-sex facilities and programs is not, as such, discriminatory under Title IX. Consequently, the Department does not believe an interpretation of Title IX that would prohibit gender identity discrimination is compatible with the statute's overall approach towards what

¹¹¹ 84 FR 27872 ("Upon publication of this notice of proposed rulemaking, the Department will, as a matter of enforcement discretion, suspend all subregulatory guidance issued before this proposed rule that interprets or implements Section 1557 (including FAQs, letters, and the preamble to [the 2016 Rule]) that is inconsistent with any provision in this proposed rule (including the preamble) or with the requirements of the underlying civil rights statutes cross-referenced by Section 1557 or their implementing regulations.").

¹¹² "Promoting the Rule of Law Through Improved Agency Guidance Documents," Exec. Order No. 13891, 84 FR 55235 (Oct. 9, 2019).

¹¹³ 81 FR 31387–88, 31467.

¹¹⁴ 81 FR 31471.

¹¹⁵ See *G.G. ex rel. Grimm v. Gloucester Cty. Sch. Bd.*, 822 F.3d 709 (4th Cir. 2016), *recurring mandate & issuing stay*, 136 S. Ct. 2442 (2016).

¹¹⁶ See, e.g., *N. Haven Bd. of Ed. v. Bell*, 456 U.S. 512, 517–20, (1982); *Cannon v. Univ. of Chi.*, 441 U.S. 677, 680 (1979).

¹¹⁷ Order, *R.G. & G.R. Harris Funeral Homes v. EEOC*, No. 18–107 (U.S. Apr. 22, 2019) (granting certiorari).

¹¹⁸ See *Glenn v. Brumby*, 663 F.3d 1312 (11th Cir. 2011).

¹¹⁹ *United States v. Virginia*, 518 U.S. 515, 516 (1996).

¹²⁰ 42 U.S.C. 2000e–2(e)(1).

¹²¹ 20 U.S.C. 1681.

¹²² 20 U.S.C. 1686.

¹²³ 45 CFR 86.32–34, § 86.41.

does and does not constitute sex discrimination.

Case law under both Title VII and Title IX has likewise recognized that these statutes do not forbid reasonable and relevant distinctions between the sexes.¹²⁴ As the United States Solicitor General recently put it, “Many commonplace practices that distinguish between the sexes do not violate [Title VII] because they account for real physiological differences between the sexes without treating either sex less favorably.”¹²⁵ No express statutory carve-out is required in order for employers under Title VII to be permitted to impose a sex-specific dress code that burdens men and women equally, nor in order for educational institutions under Title IX to be permitted to require men and women to shower separately from each other. And as compared to the fields of employment and of education, the field of healthcare necessarily may contain many more “commonplace practices that distinguish between the sexes . . . [by] account[ing] for real physiological differences between the sexes without treating either sex less favorably.” As discussed in greater detail later in the subsection of this preamble on gender identity, reasonable distinctions between the sexes may be called for in numerous areas within the Department’s expertise, including shared hospital rooms,¹²⁶ sex-specific protections for patients’ modesty,¹²⁷ specialized medical practices related to gynecology,¹²⁸ and medical treatments

or recommendations relying on sex-based generalizations,¹²⁹ and other research situations.¹³⁰ The biological differences between men and women are not irrelevant to employment law and education, and they are in many ways even more relevant in the health setting.

In general, a covered entity is permitted to make distinctions on the basis of sex that are “not marked by misconception and prejudice, nor . . . show disrespect for either class.”¹³¹ In many cases, removing or weakening such reasonable sex-based distinctions could undermine the equality of the sexes by disproportionately harming women.¹³² As discussed further below, case law is still developing as to whether covered entities’ refusal to draw these distinctions could in some cases violate personal privacy interests and so create a hostile environment under Title IX.¹³³ “[N]eutral terms can mask discrimination that is unlawful,” while “gender specific terms can mark a permissible distinction.”¹³⁴ Where the “[p]hysical differences between men and women” are relevant, sex-neutral policies will in some cases “undoubtedly require alterations” to make them sex-specific, in order “to afford members of each sex privacy from the other sex in living arrangements.”¹³⁵

Comment: Commenters stated that *Price Waterhouse v. Hopkins*, 490 U.S.

Administration, Dec. 17, 2019 (HRSA) <https://www.hrsa.gov/womens-guidelines-2019>.

¹²⁹ See the Department’s Office of Women’s Health, <https://www.womenshealth.gov/>.

¹³⁰ See NIH Guidance, *Consideration of Sex as a Biological Variable in NIH-funded Research* (2017), https://orwh.od.nih.gov/sites/orwh/files/docs/NOT-OD-15-102_Guidance.pdf; NIH, Office of Research on Women’s Health, “Sex & Gender,” <https://orwh.od.nih.gov/>.

¹³¹ See *Tuan Anh Nguyen v. INS*, 533 U.S. 73.

¹³² See Brief for EEOC, *Harris Funeral Homes*, at 37–38 (citing cases).

¹³³ See, e.g., *Doe v. Luzerne Cty.*, 660 F.3d 169, 176–77 (3d Cir. 2011) (recognizing that an individual has “a constitutionally protected privacy interest in his or her partially clothed body” and that this “reasonable expectation of privacy” exists “particularly while in the presence of members of the opposite sex”); *Brannum v. Overton Cty. Sch. Bd.*, 516 F.3d 489, 494 (6th Cir. 2008) (“the constitutional right to privacy . . . includes the right to shield one’s body from exposure to viewing by the opposite sex”); *Fortner v. Thomas*, 983 F.2d 1024, 1030 (11th Cir. 1993) (“[M]ost people have a special sense of privacy in their genitals, and involuntary exposure of them in the presence of people of the other sex may be especially demeaning or humiliating.”). But see *Parents for Privacy v. Barr*, No. 18–35708, (9th Cir. Feb. 12, 2020) (no title IX or constitutional privacy violation for school policy allowing student to use bathroom and locker rooms consistent with their gender identity).

¹³⁴ *Tuan Anh Nguyen v. INS*, 533 U.S. 64.

¹³⁵ *United States v. Virginia*, 518 U.S. 515, 550 n.19 (1996) (emphasis added) (brackets and citation omitted).

228 (1989), and *Oncale v. Sundowner Offshore Oil Services, Inc.*, 523 U.S. 75 (1998), fully support or even require the 2016 Rule’s gender identity provisions or their equivalent. Commenters asked the Department to address specific court cases that they stated were contrary to the Department’s view, such as *Doe v. Boyertown Area Sch. Dist.*, 897 F.3d 518 (3d Cir. 2018), *Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034 (7th Cir. 2017), and *Glenn v. Brumby*, 663 F.3d 1312 (11th Cir. 2011).

Response: For most of the history of Title IX case law, the “commonplace practices that . . . account for real physiological differences between the sexes without treating either sex less favorably”¹³⁶ were uncontroversial and not considered discriminatory. In the past five years, two circuit courts have begun to question this long-standing precedent in proceedings arising from motions for preliminary injunctions, although no circuit court has yet done so in a final ruling.¹³⁷

These courts (and some district courts) draw on the Supreme Court’s reasoning in *Price Waterhouse* in order to assert that otherwise permissible distinctions on the basis of sex must be applied (if at all) on the basis of an individual’s subjective gender identity. But the novel legal theory advanced by these courts represents a serious misreading of *Price Waterhouse* and of Title IX, a reading that has been disputed by the decisions of other courts, including *Franciscan Alliance*.

Price Waterhouse is a Title VII case and establishes that, “[i]n forbidding employers to discriminate against individuals because of their sex, Congress intended to strike at the entire spectrum of disparate treatment of men and women resulting from sex stereotypes.”¹³⁸

When courts have read *Price Waterhouse* as determining that “on the basis of sex” encompasses gender identity, they have done so on the ground that discrimination on the basis of gender identity is, as such, a form of sex stereotyping. But *Price Waterhouse* should be read in light of the Supreme Court definition of a “stereotype” about sex “as a frame of mind resulting from

¹³⁶ Brief for EEOC, *Harris Funeral Homes*, at 36.

¹³⁷ *Whitaker v. Kenosha Unified Sch. Dist.*, 858 F.3d 1034, 1039 (7th Cir. 2017); *Dodds v. United States Dep’t of Educ.*, 845 F.3d 217 (6th Cir. 2016). The ruling in a third related case, *G.G. v. Gloucester Co. Sch. Bd.*, 822 F.3d 709 (4th Cir. 2016), was based on *Auer* deference to Department of Education subregulatory guidance and has since been vacated after that guidance was withdrawn.

¹³⁸ *Price Waterhouse v. Hopkins*, 490 U.S. 228, 251 (1989), quoting *Los Angeles Dept. of Water & Power v. Manhart*, 435 U.S. 702, 707, n. 13 (1978).

¹²⁴ See *Wittmer v. Phillips 66 Co.*, 915 F.3d 328, 334 (5th Cir. 2019) (Ho, J., concurring); *Jespersen v. Harrah’s Operating Co.*, 444 F.3d 1104, 1109–10 (9th Cir. 2006) (en banc) (collecting cases).

¹²⁵ Brief for EEOC, *R.G. & G.R. Harris Funeral Homes v. EEOC*, No. 18–107 (U.S. filed Aug. 16, 2019), at 36.

¹²⁶ See *Cypress v. Newport News General and Nonsectarian Hospital Association*, 375 F.2d 648, 658 (4th Cir. 1967) (“Our holding is simply that race cannot be a factor in the admission, assignment, classification, or treatment of patients in an institution like this, which is state-supported and receives federal funds. Room assignments may be made with due regard to sex, age, type of illness, or other relevant factors, but racial distinctions are impermissible, since the law forbids the treatment of individuals differently or separately because of their race, color, or national origin.”); cf. similar statutory requirements at 10 U.S.C. 4319 (Army), 10 U.S.C. 6931 (Navy), and 10 U.S.C. * 9319 (Air Force) (requiring separation of sleeping and latrine areas for “male” and “female” recruits); 10 U.S.C. 4320 (Army), 10 U.S.C. 6932 (Navy), and 10 U.S.C. 9320 (Air Force) (limiting after-hours access by drill sergeants and training personnel to persons of the “same sex as the recruits”).

¹²⁷ See, e.g., OCR Voluntary Resolution Agreement with Michigan State University, <https://cms-drupal-hhs-prod.cloud.hhs.gov/sites/default/files/vra-between-msu-and-ocr.pdf>, at IV.D.1.d.iii, IV.D.1.d.v.

¹²⁸ See, e.g., Women’s Preventive Services Guidelines, Health Resources and Services

irrational or uncritical analysis.”¹³⁹ Wherever “stereotyping play[s] a motivating role in an employment decision,” according to *Price Waterhouse*, the employer has demonstrated an “impermissible motive,” for stereotypes should not even “play a part in the decisionmaking process.”¹⁴⁰

The Department believes that, unlike stereotypes, reasonable distinctions on the basis of sex, as the biological binary of male and female, may, and often must, “play a part in the decisionmaking process”—especially in the field of health services. A covered entity such as a healthcare provider is not impermissibly stereotyping biological males (notwithstanding their internal sense of gender) on the basis of sex if it uses pronouns such as “him”; limits access to lactation rooms and gynecological practices to female users and patients; or lists a male’s sex as “male” on medical forms. Similarly, a covered health care entity is not impermissibly stereotyping biological females (notwithstanding their internal sense of gender) on the basis of sex if it uses pronouns such as “her”; warns females that heart-attack symptoms are likely to be quite different than those a man may experience; advises women that certain medications tend to affect women differently than men; or lists a female’s sex as “female” on medical forms. Finally, it is not stereotyping for covered entities to have bathrooms or changing rooms designated by reference to sex, or to group patients in shared hospital rooms by sex.¹⁴¹ Such practices and actions are not rooted in stereotypes, but in real biological or physiological differences between the sexes. Moreover, none of these examples disadvantages one sex over another, and in fact the failure to take sex into account may in some cases have a disadvantageous effect.

As the Supreme Court has noted, “to fail to acknowledge even our most basic biological differences . . . risks making the guarantee of equal protection superficial, and so disserving it. Mechanistic classification of all our

differences as stereotypes would operate to obscure those misconceptions and prejudices that are real.”¹⁴² “[T]here is nothing irrational or improper in the recognition” of the social and other consequences of real physiological differences between the sexes; “[t]his is not a stereotype.”¹⁴³ Reasonable distinctions “may be based on real differences between the sexes . . . so long as the distinctions are not based on stereotyped or generalized perceptions of differences.”¹⁴⁴ “Prohibition of harassment on the basis of sex requires neither asexuality nor androgyny.”¹⁴⁵

Justice Ginsburg’s majority opinion in *U.S. v. Virginia* sharply distinguished sex from other protected classes in this regard: “Supposed ‘inherent differences’ are no longer accepted as a ground for race or national origin classifications. Physical differences between men and women, however, are enduring: ‘[T]he two sexes are not fungible; a community made up exclusively of one [sex] is different from a community composed of both.’ . . . ‘Inherent differences’ between men and women, we have come to appreciate, remain cause for celebration.”¹⁴⁶ This recognition of physical (*i.e.*, biological) differences between men and women is not stereotyping and in some cases will “undoubtedly require alterations” to accommodated sex-specific differences.¹⁴⁷

The lower court decisions referenced by commenters held that a covered entity which required transgender individuals to abide by otherwise permissible distinctions on the basis of sex, such as separate-sex bathrooms, would be impermissibly “imposing its stereotypical notions of how sexual organs and gender identity ought to align.”¹⁴⁸ A few lower courts have

relied on these holdings in interpreting Section 1557 to require covered entities to override these reasonable distinctions based on sex, in deference to an individual’s gender identity.¹⁴⁹ The notion that such distinctions on the basis of sex amount, as such, to impermissible stereotyping, would be lethal to countless reasonable and fully permissible healthcare practices, some of which have been identified above. No court has gone so far: These lower courts have questioned such distinctions only insofar as these distinctions come into conflict with an individual’s stated gender identity. But *Price Waterhouse* offers no basis for this regime of individualized exceptions to otherwise reasonable distinctions. If it is impermissible stereotyping of a female employee to demand that she not “behave aggressively,” then *Price Waterhouse* (to the extent that it applies) requires companies to stop holding *all* female employees to such a stereotyped standard—not merely to grant exceptions for the occasional female employee who objects to that standard.¹⁵⁰ Similarly, if it is impermissible stereotyping to assume that “sexual organs . . . ought to align” with the sex listed on one’s hospital bracelet, then *Price Waterhouse* (to the extent that it applies) would invalidate the existence of *all* sex markers on hospital bracelets, not merely of those to which a transgender individual has objected. Where a covered entity has not stereotyped but has only drawn a reasonable distinction, *Price Waterhouse* is irrelevant.

Distinctions based on real differences between men and women do not turn into discrimination merely because an individual objects to those distinctions. Title IX does not require covered entities to eliminate reasonable distinctions on the basis of sex whenever an individual identifies with the other sex, or with no sex at all, or with some combination of the two sexes

to the sex-based stereotypes associated with their assigned sex at birth, differently. These students are disciplined under the School District’s bathroom policy if they choose to use a bathroom that conforms to their gender identity.”); *Glenn v. Brumby*, 663 F.3d 1312, 1316 (11th Cir. 2011) (“A person is defined as transgender precisely because of the perception that his or her behavior transgresses gender stereotypes.”).

¹⁴⁹ See *Rumble v. Fairview Health Servs.*, No. 14–cv–037 (SRN/FLN), 2017 WL 401940 (D. Minn. Jan. 30, 2017); *Prescott v. Rady Children’s Hospital-San Diego*, 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017)

¹⁵⁰ See *Price Waterhouse*, 490 U.S. at 235, 250–51.

¹³⁹ *Tuan Anh Nguyen v. I.N.S.*, 533 U.S. 53, 68 (2001).

¹⁴⁰ *Price Waterhouse*, 490 U.S. 252–53, 254–55. The Civil Rights Act of 1991 amends the *Price Waterhouse* standard to say that “an unlawful employment practice is established when the complaining party demonstrates that . . . sex . . . was a motivating factor for any employment practice, even though other factors also motivated the practice,” but the employer may rebut this claim if he or she “demonstrates that [the employer] would have taken the same action in the absence of the impermissible motivating factor.” 42 U.S.C. 2000e–2(m), § 2000e–5(g)(2)(B).

¹⁴¹ See 29 CFR 1910.141(c) (OSHA regulation requiring “toilet rooms separate for each sex”).

¹⁴² *Tuan Anh Nguyen*, 533 U.S. at 73. In *Sessions v. Morales-Santana*, 137 S. Ct. 1678 (2017), the Supreme Court struck down, on intermediate-scrutiny grounds, a statute that granted U.S. citizenship to children born abroad of unwed parents if the child’s mother had been a U.S. citizen for one year before the birth, but required five years in the case of a U.S. citizen father. However, the Court did not reject the *Nguyen* analysis recognizing that sex distinctions are real, and that not all such distinctions are based on unlawful stereotypes.

¹⁴³ *Id.* at 68.

¹⁴⁴ *Faulkner v. Jones*, 10 F.3d 226, 232 (4th Cir. 1993).

¹⁴⁵ *Oncale v. Sundowner Offshore Oil Services, Inc.*, 523 U.S. 75, 81 (1998).

¹⁴⁶ *United States v. Virginia*, 518 U.S. 515, 533 (1996) (internal citations omitted).

¹⁴⁷ *Id.* at 550 n.19.

¹⁴⁸ *Equal Employment Opportunity Comm’n v. R.G. & G.R. Harris Funeral Homes, Inc.*, 884 F.3d 560, 576 (6th Cir. 2018). See also *Whitaker v. Kenosha Unified Sch. Dist.*, 858 F.3d 1034, 1051 (7th Cir. 2017) (“the School District treats transgender students like Ash, who fail to conform

(as under the 2016 Rule).¹⁵¹ Rather, Title IX prohibits subjecting a person to less favorable treatment because of his or her sex. Thus, if a person claims to have been discriminated against on the basis of his or her sex, that claim is neither weakened nor strengthened by any allegations about his or her “internal sense of gender.” Numerous lower courts have held that, like any other man or woman, a transgender individual may sue under Title VII if he or she is harassed, assaulted, terminated, or otherwise discriminated against because of his or her sex.¹⁵² Under Title IX, as under Title VII, “[t]ranssexuals are not genderless, they are either male or female and are thus protected under Title VII to the extent that they are discriminated against on the basis of sex.”¹⁵³ The Department will vigorously enforce Section 1557’s prohibition on sex-based discrimination, but that prohibition cannot be construed as a prohibition on reasonable sex-based distinctions in the health field.

Comment: Commenters offered a variety of views on the role that a patient’s sex and/or gender identity ought to play in medical decision-making.

Many commenters spoke of the importance of sex-reassignment surgeries and cited studies that they said show the value of these surgeries in alleviating gender dysphoria. Others cited different studies that they said

show the opposite. Some clinicians expressed concerns about consent and medical appropriateness of pre-pubertal sex reassignment with lifelong physical and mental implications (including permanent sterility) when children and adolescents lack the requisite social, emotional, and intellectual maturity, or life experiences necessary for true consent. Commenters also were concerned about coercive, peer, adult, and ideological pressures on children and adolescents to seek cross-sex hormonal treatment, sex reassignment surgery, or other similar services. Some commenters, including parties to lawsuits against the Department on the ground that the 2016 Rule would require gender transition treatments and therapies for children, criticized the 2016 Rule for containing no age limitation. Commenters stated that the “gender-affirming” model is the most controversial form of counseling and, as such, is not used by the Dutch national transgender clinic, which they said is considered the international flagship of gender dysphoria treatment.

Some commenters noted that violations of the 2016 Rule are enforceable by termination of Federal financial assistance and that violations of State law with respect to healthcare may involve civil penalties for negligence or malpractice, etc. In light of this, they stated that the 2016 Rule placed providers in an impossible position, where compliance with one law means noncompliance with another, and either choice results in a steep penalty.

Other commenters said that the 2016 Rule’s definition of “on the basis of sex” could prohibit the way OB/GYN practices specialize in treating females, and raised the concern that specializing in the treatment of female patients could be deemed prohibited discrimination against biological males who identify as women. Commenters stated that because these services are focused on and tailored to females as a single biological sex, they are able to provide a higher quality of care to those patients. They noted that it has long been a permissible sex-based distinction for OB/GYN doctors to not treat any biological males, and this distinction is recognized under HHS Title IX regulations. Such commenters found the 2016 Rule overbroad and inconsistent with day-to-day affairs in how they practice medicine. But other commenters stated that OB/GYNs are not affected by the transgender requirements under the 2016 Rule and that pre-existing OB/GYN practices are justified by reasonable scientific justifications.

Certain providers advocated for removal of the requirement to “treat individuals consistent with their gender identity,” as this provision would violate the conscience rights of healthcare providers, and the ethical and foundational convictions that underlie the entire way they practice medicine. Other commenters said that repeal of this provision leaves no clarity about whether such providers will actually provide treatment for transgender patients, and expressed the concern that affirming treatment consistent with gender identity is necessary for high-value transgender healthcare, as is required for all people in the practice of medicine.

Some commenters noted their concern that the 2016 Rule requires doctors to remove healthy reproductive tissue in sex-reassignment surgeries, even if it may be contrary to the patient’s medical interest. For example, if a surgeon performs mastectomies as part of a medically necessary treatment for breast cancer, under the 2016 Rule, he or she could also have been required to perform mastectomies for sex-reassignment purposes when recommended by a psychologist, even if the surgeon believes such treatments are not medically indicated in his or her own professional judgment. Similarly, commentators argued that some doctors might be forced to perform hysterectomies not only against their medical judgment but also outside of their expertise. Other commenters contended that certain procedures are not meaningfully different when performed on a transgender versus non-transgender patient, because the mechanics of the procedures are substantially similar. Although genital reassignment surgery is considered a “gender transition service,” clinicians commented that somewhat similar procedures are used for genital reconstruction to repair damaged, diseased, or disfigured genital tissue, or in the treatment of disorders of sexual development.

Commenters also stated that the 2016 Rule would force them to provide services damaging to the health of patients, in conflict with their mission as a healthcare provider, instead of using these medical resources to help patients.¹⁵⁴

Commenters stated that HHS does not have a compelling interest in requiring the medical provision of, or insurance

¹⁵¹ See *Johnston v. Univ. of Pittsburgh of the Commonwealth Sys. of Higher Educ.*, 97 F. Supp. 3d 657 (W.D. Pa. 2015).

¹⁵² *Barnes v. City of Cincinnati*, 401 F.3d 729 (6th Cir. 2005); *Smith v. City of Salem*, 378 F.3d 566 (6th Cir. 2004). These cases have been cited, by the 2016 Rule and in some recent court cases, in support of the view that sex discrimination encompasses discrimination on the basis of gender identity. This is a serious misreading pointed out at *Johnston v. Univ. of Pittsburgh of Com. Sys. of Higher Educ.*, 97 F. Supp. 3d 657, 675n17 (W.D. Pa. 2015) (“In *Smith v. City of Salem*, . . . the court did not conclude that “transgender” is a protected class under Title VII, but only that a male or female who is also transgender can assert a sex stereotyping claim under Title VII for adverse employment actions that result from the individual’s conformity to their gender identity rather than their biological or birth sex. Indeed, the same year that the 6th Circuit issued its opinion in *Smith*, it affirmed, in an unpublished opinion, a district court decision holding that “Title VII does not prohibit discrimination based on an individual’s status as a transsexual,” in an employment discrimination case involving a transgender women’s use of a men’s restroom. *Johnson v. Fresh Mark, Inc.*, 98 Fed. App’x. 461, 462 (6th Cir.2004).”).

¹⁵³ *Tronetti v. TLC HealthNet Lakeshore Hosp.*, No. 03–CV–0375E(SC), 2003 WL 22757935, at *4 (W.D.N.Y. Sept. 26, 2003). See *Rosa v. Park West Bank Trust Co.*, 214 F.3d 213, 215–16 (1st Cir. 2000) (discrimination against a cross-dressing man is sex-based discrimination if the entity would have treated a “similarly situated” woman differently, i.e., if it treats “a woman who dresses like a man differently than a man who dresses like a woman”).

¹⁵⁴ Commenters cited specific examples of coercion. See *Minton v. Dignity Health*, 2017 WL 7733922 (Cal. Super. Ct. Nov. 2017); *Robinson v. Dignity Health*, No. 16–cv–3035 YGR, 2016 WL 7102832 (N.D. Cal. Dec. 6, 2016) (on remand from U.S. Supreme Court).

for, gender transition services or procedures. Other commenters stated that access to such services for transgender patients constitutes a compelling interest. Some commenters challenged the idea that an individual born as one biological sex can in actuality be transformed into a person of the other sex, with or without surgeries or hormone treatments.

Response: The Department recognizes that certain single-sex medical procedures, treatments, or specializations are rooted in the binary and biological meaning of sex for valid scientific and medical reasons. The Department believes the 2016 Rule caused significant confusion and cast doubt as to whether such longstanding specialized practices remained lawful, as indicated, for example, by the fact that commenters had diverging views on how the 2016 Rule impacted OB/GYN practices. The Department declines to interfere in these practices, and repeals a mandate that was, at least, ambiguous and confusing.

The Department appreciates the many comments received on the issue of gender identity, gender dysphoria, and the appropriate care for individuals with gender dysphoria. The Department believes providers should be generally free to use their best medical judgment, consistent with their understanding of medical ethics, in providing healthcare to Americans. The wide variation in these comments confirms that the medical community is divided on many issues related to gender identity, including the value of various “gender-affirming” treatments for gender dysphoria (especially for minors), the relative importance of care based on the patient’s sex, and the compatibility of gynecological practice with a requirement of nondiscrimination on the basis of gender identity.¹⁵⁵

The Department is also reluctant to pretermitt ongoing medical debate and study about the medical necessity of gender transition treatments. The 2016 Rule assumed that, if a covered entity offers a “categorical coverage exclusion or limitation for all health services related to gender transition,” then that entity must be relying on medical judgments that are “outdated and not based on current standards of care.”¹⁵⁶ But based on its review of the most recent evidence, the Department concludes that this was an erroneous assertion, and that there is, at a

minimum, a lack of scientific and medical consensus to support this assertion, as the comments noted above demonstrate. This lack of scientific and medical consensus—and the lack of high-quality scientific evidence supporting such treatments—is borne out by other evidence. For example, on August 30, 2016, CMS declined to issue a National Coverage Determination (NCD) on sex-reassignment surgery for Medicare beneficiaries with gender dysphoria “because the clinical evidence is inconclusive.”¹⁵⁷ CMS determined, “[b]ased on an extensive assessment of the clinical evidence,” that “there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.”¹⁵⁸ Similarly, in a 2018 Department of Defense (DOD) report on the diagnosis of gender dysphoria, which included input from both transgender individuals and medical professionals with experience in the care and treatment of individuals with gender dysphoria, DOD found that there is “considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments, such as cross-sex hormone therapy and sex reassignment surgery—interventions which are unique in psychiatry and medicine—remedy the multifaceted mental health problems associated with gender dysphoria.”¹⁵⁹ Other research has found that children who socially transition in childhood faced dramatically increased likelihood of persistence of gender dysphoria into adolescence and adulthood.¹⁶⁰ The Department does not believe that the nondiscrimination requirements in Title IX, incorporated by reference into Section 1557, foreclose medical study or debate on these issues. And to the extent that a medical consensus develops on these issues, it is not clear that regulations of the sort encompassed

in the 2016 Rule would be necessary to encourage medical professionals to follow such consensus.

The Department believes that its approach in the 2016 Rule inappropriately interfered with the ethical and medical judgment of health professionals. The preamble to the 2016 Rule stated that, under that Rule, “a provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to provide the procedure for transgender individuals in the same manner it provides the procedure for other individuals.”¹⁶¹ This statement raised the prospect of forcing a provider to perform irreversible, sterilizing, and endocrine-disrupting procedures on what may be, in the provider’s view, non-diseased and properly functioning organs—including in children and youth.¹⁶² A medical provider may rightly judge a hysterectomy due to the presence of malignant tumors to be different in kind from the removal of properly functioning and healthy reproductive tissue for psychological reasons, even if the instruments used are identical. For example, OB/GYNs competent and willing to perform dilation and curettage procedures to aid with recovery from a miscarriage should not, and legally cannot,¹⁶³ be forced to perform dilation and curettage procedures for abortions, because the regulatory, ethical, and medical frameworks that apply to abortions are radically different from those that apply to recovery from miscarriages. Moreover, commenters who offer transition services made clear that these often involve specialized cross-sex hormonal treatments before and after any sex-reassignment surgeries, and require coordination of care with urologists, psychiatrists, and a variety of other healthcare professionals in different specialized fields. A provider who routinely provides, for example, hysterectomies to address uterine cancer should be able reasonably to choose not to be involved in what may be the much more medically complicated set of procedures involved in sex reassignment.

¹⁵⁵ Comments referring specifically to providers’ conscientious objections to certain forms of treatment are addressed below in the section on “relation to other laws.”

¹⁵⁶ Cf. 81 FR 31472, 31429.

¹⁵⁷ CMS, “Decision Memo for Gender Dysphoria and Gender Reassignment Surgery” (CAG-00446N) (Aug. 30, 2016) <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=282>.

¹⁵⁸ *Id.*

¹⁵⁹ Department of Defense, “Report and Recommendations on Military Service by Transgender Persons” (Feb. 22, 2018), 5.

¹⁶⁰ Thomas D. Steensma, Ph.D., Jenifer K. McGuire, Ph.D. M.P.H., et al. “Factors Associated with Desistance and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study,” 52(6) *Journal of the American Academy of Child & Adolescent Psychiatry* 582–90 (2013).

¹⁶¹ 81 FR 31455.

¹⁶² In this regard, the Department distinguishes between the situation created by the requirements of 2016 Rule and the in-program requirements applied within federally funded grant programs where, for example, “the general rule that the Government may choose not to subsidize speech applies with full force,” even if the speech concerns what is allegedly required by medical ethics. *See, e.g., Rust v. Sullivan*, 500 U.S. 173, 200 (1991).

¹⁶³ *See Church Amendments*, 42 U.S.C. 300a–7.

Upon reconsidering this issue, the Department now believes that the 2016 Rule did not offer a sufficient analysis to justify the serious effect of requiring providers to perform certain procedures or provide certain treatments contrary to their medical judgment. The Department does not and need not take a definitive view on any of the medical questions raised in these comments about treatments for gender dysphoria. The question is whether Title IX and Section 1557 require healthcare professionals, as a matter of nondiscrimination, to perform such procedures or provide such treatments. The answer is that they do not. This final rule does not presume to dictate to medical providers the degree to which sex matters in medical decision making, nor does it impose the 2016 Rule's vague and overbroad mandate that they "treat individuals consistent with their gender identity."

Nothing in this final rule prohibits a healthcare provider from offering or performing sex-reassignment treatments and surgeries, or an insurer from covering such treatments and procedures, either as a general matter or on a case-by-case basis. The large number of comments received from healthcare providers who perform such treatments and procedures suggests that there is no shortage of providers willing to do so, even without the 2016 Rule's provisions on gender identity (which had been enjoined for over two years by the time of the comment period).

Finally, the *Franciscan Alliance* court held that HHS had not demonstrated a compelling interest in requiring providers with sincerely held religious objections to gender transition services, notwithstanding their objections, to provide these services. The Department sees no compelling interest in forcing the provision, or coverage, of these medically controversial services by covered entities, much less in doing so without a statutory basis.

Comment: Some commenters stated that revising the rule to eliminate the court-vacated provisions on gender identity, in conjunction with other Federal actions related to gender transition-related services, is evidence of animus to transgender individuals, and that the free exercise of religion or conscience claims raised by medical professionals and insurers are merely "pretext" for invidious discrimination. Others contended that the proposed rule recognizes the human dignity of all because certain surgical procedures and medications related to gender identity and abortion do not actually serve the health or wellbeing of patients but violate their dignity and physical and

psychological integrity, especially of children and women in crisis pregnancies, and that these providers act out of sincere beliefs both as to medical judgment and religious belief in pursuing the best interests of patients regardless of their background or stated identities.

Response: The Department respects the dignity of all individuals. It seeks to further the health and well-being of all, but it can do so only by implementing the laws as adopted by Congress.

Moreover, the Department notes that commenters have provided a number of bases for objections to being forced to provide or cover certain treatments or surgeries contrary to their sincere medical, economic, religious, scientific, ethical, or conscience-based reasons. To presume that religious beliefs on these issues are rooted in bigotry, animosity, or insincerity would risk unlawfully stereotyping people of faith. See *Masterpiece Cakeshop v. Colorado Civil Rights Comm'n*, 138 S. Ct. 1719, 1729 (2018) ("To describe a man's faith as 'one of the most despicable pieces of rhetoric that people can use' is to disparage his religion in at least two distinct ways: By describing it as despicable, and also by characterizing it as merely rhetorical—something insubstantial and even insincere.").¹⁶⁴

Comment: Commenters expressed various views on whether transgender patients should be treated in accord with their expressed gender identity and/or in accord with their sex.

Some commenters stated that transgender designations conceal real biological sex differences that are relevant to medical risk factors, recognition of which is important for effective diagnosis, treatment, and disease prevention—including effective treatment for patients who identify as transgender. Some added that biological sex differences remain present in numerous bodily systems even after a patient has undergone hormonal and/or surgical transition therapies, and that physicians must be permitted to take these differences into account. Healthcare providers commented that critical decisions are made in the practice of medicine on the basis of objective biological information concerning a person's sex as being male or female because, among other reasons, medications and treatments affect males and females differently, and only females can become pregnant, regardless of stated gender identity. These commenters were concerned that by

requiring providers to treat patients consistent with gender identity instead of biological sex, the patients' health is endangered, with both short- and long-term consequences.¹⁶⁵

Other commenters stated that the Department has not provided sufficient explanation or justification for removing § 92.206 of the 2016 Rule with respect to ensuring equal access to healthcare services without respect to sex, including prohibitions on discriminatory denials of services typically associated with one sex to persons who identify as transgender. The commenters stated that the Department ignored the text of § 92.206 when it asserted in the proposed rule that the 2016 Rule would "require[e] healthcare entities to code as male all persons who self-identify as male, regardless of biology, [which] may lead to adverse health consequences."¹⁶⁶ Commenters said § 92.206 properly prohibits, among other things, the arbitrary denial of care based not on clinical considerations but solely on the patient's "sex as assigned at birth" or as recorded in medical or insurance records. Others said that while the biological definition of "sex" may be appropriate for scientific contexts such as National Institutes of Health ("NIH") studies, the Department's nondiscrimination provisions should define the term more broadly.

Some commenters commented on a case of a transgender patient with abdominal pains who, as a result of being treated according to a male gender identity, was not diagnosed as being pregnant as part of the triage process and had a stillborn child. Some commenters viewed this set of facts as evidence against the 2016 Rule while others claimed it was evidence for the 2016 Rule.

Response: The Department has long recognized that the practice of medicine and biomedical research routinely involves decisions and diagnoses that legitimately make distinctions based on sex, including decisions made at triage; research studies (including clinical trials); questions of medical history; and requests for a medical consultation. As discussed at length in the NPRM, substantial scientific literature published after the 2016 Rule indicates that sex-specific practices in medicine and research exist because biological

¹⁶⁴ Religious exemptions will be addressed further in the section discussing the final rule's relation to other laws.

¹⁶⁵ Commenters cited texts including William J. Malone, MD, *Gender Dysphoria Resource for Providers* (3rd Edition); and Michael Laidlaw, MD, "The Gender Identity Phantom," International Discussion Space for Clinicians and Researchers (Oct. 24, 2018) <http://gdworkinggroup.org/2018/10/24/the-gender-identity-phantom>.

¹⁶⁶ See 84 FR 27885, n. 55.

(and, derivatively, genetic) differences between males and females are real and matter to health outcomes and research.¹⁶⁷ For example, NIH requires research grant applicants to consider sex as a biological variable “defined by characteristics encoded in DNA, such as reproductive organs and other physiological and functional characteristics.”¹⁶⁸ According to an NIH article,

[s]ex as a biological variable (SABV) is a key part of the new National Institutes of Health (NIH) initiative to enhance reproducibility through rigor and transparency. The SABV policy requires researchers to factor sex into the design, analysis, and reporting of vertebrate animal and human studies. The policy was implemented as it has become increasingly clear that male/female differences extend well beyond reproductive and hormonal issues. Implementation of the policy is also meant to address inattention to sex influences in biomedical research. Sex affects: Cell physiology, metabolism, and many other biological functions; symptoms and manifestations of disease; and responses

to treatment. For example, sex has profound influences in neuroscience, from circuitry to physiology to pain perception.¹⁶⁹

Yet the 2016 Rule required covered entities to “treat individuals consistent with their gender identity” in virtually every respect. The 2016 Rule’s definition of gender identity does not turn on any biological or external indicia of sex, and explicitly disavows any such reliance.¹⁷⁰ Under the 2016 Rule, one can identify as “male, female, neither, or a combination of male and female.” A person’s gender identity under the 2016 Rule is determined ultimately by what a person says his or her gender identity is, and a covered entity is bound to treat all individuals “consistent with their gender identity” the moment it becomes aware of such a declaration (which must be allowed to change under the 2016 Rule). No other Federal statute, agency rule, or guidance has ever gone so far on this question.¹⁷¹

In this regard, the 2016 Rule risked masking clinically relevant, and sometimes vitally important, information by requiring providers and insurers to switch from a scientifically valid and biologically based system of tracking sex to one based on subjective self-identification according to gender identity. By eliminating the transgender provisions and definitions from the 2016 Rule, this final rule clarifies that sex, according to the Title IX’s plain meaning, may be taken into account in the provision of healthcare, insurance (including insurance coverage), and health research, as was the practice before the 2016 Rule.

Section 92.206 of the 2016 Rule required covered entities to “treat individuals consistent with their gender identity” in every respect save one. Namely, “a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual’s sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are

ordinarily or exclusively available.” This confusingly worded exception is premised on the fact that entities may provide specific services to “one sex” based on biology, yet must grant transgender individuals access to such single-sex services regardless of how they identify *and* regardless of their sex (“sex assigned at birth”). The 2016 Rule’s mandate cannot answer, for example, how a provider is to determine whether or when a transgender individual is entitled by law to be referred to a women’s mental health support group, a men’s mental health support group, either group, or both at the same time.

Some providers choose to code and track patients according to their biology for some purposes and according to their gender identity for other purposes. Under the 2016 Rule, however, if a transgender patient self-identifies as male in the medical intake process, yet an examining doctor has reason to believe the patient is biologically female, the doctor could reasonably assume that he or she is *prohibited* from changing the person’s chart to reflect female sex, because that would not be treating the person “consistent with” her stated gender identity.

In the 2019 NPRM, the Department cited a 2019 case from a medical journal article that concluded that a nurse had applied longstanding standards when triaging what the article called a “man with abdominal pain,” who identified as male and had been classified as such, but who was in fact a pregnant woman.¹⁷² Because indications of pregnancy were not manifest, and because the patient was treated according to stated gender identity, her pregnancy was not diagnosed early, and the child was stillborn.

This provider was treating the patient according to her stated gender identity (male), just as the 2016 Rule demanded. Indeed, the provider risked liability under the 2016 Rule for not taking that step. The provider did not act unreasonably when, consistent with longstanding medical practice, it did not have a policy of asking every man with abdominal pain whether he is pregnant.

Unlike the many strained hypothetical objections offered in opposition to the proposed rule, this case is not based on speculation. Rather,

¹⁶⁷ See, e.g., NIH Research Matters, *Gene Linked to Sex Differences in Autism* (Apr. 14, 2020), <https://www.nih.gov/news-events/nih-research-matters/gene-linked-sex-differences-autism>; Wei Yang, Nicole M. Warrington, et al., Clinically Important Sex differences in GBM biology revealed by analysis of male and female imaging, transcriptome and survival data, *Science Translational Medicine* (Jan. 21, 2019), <https://www.ncbi.nlm.nih.gov/pubmed/306025365> (identifying sex-specific molecular subtypes of glioblastoma); Ramona Stone and W. Brent Weber, Male-Female Differences in the Prevalence of Non-Hodgkin Lymphoma, 81 *Journal of Environmental Health* 16 (Oct. 2018); <https://www.ncbi.nlm.nih.gov/pubmed/28065609>; Anke Samulowitz, Ida Gremyr, et al., “Brave Men” and “Emotional Women”: A Theory-Guided Literature Review on Gender Bias in Health Care and Gendered Norms towards Patients with Chronic Pain, *Pain Research and Management* (Feb. 25, 2018), <https://www.ncbi.nlm.nih.gov/pubmed/29682130> (stating that “the response to opioid receptor antagonists may generate a difference between men’s and women’s experiences of pain”); Douglas C. Dean III, E.M. Planalp, et al., Investigation of brain structure in the 1-month infant, *Brain Structure and Function* 1–18 (Jan. 5, 2018), <https://www.ncbi.nlm.nih.gov/pubmed/29305647> (finding differences between male and female infants at the age of 1 month); Stefan Ballestri, Fabio Nascimbeni, et al., NAFLD as a Sexual Dimorphic Disease: Role of Gender and Reproductive Status in the Development and Progression of Nonalcoholic Fatty Liver Disease and Inherent Cardiovascular Risk, *Advances in Therapy* (May 19, 2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5487879>; Susan Sullivan, Anna Campbell, et al., What’s good for the goose is not good for the gander: Age and gender differences in scanning emotion faces, 72:3 *Journals of Gerontology* 441 (May 1, 2017), <https://www.ncbi.nlm.nih.gov/pubmed/25969472>; Ester Serrano-Saiz, Meital Oren-Suissa, et al., Sexually Dimorphic Differentiation of a C. Elegans Hub Neuron Is Cell Autonomously Controlled by a Conserved Transcription Factor, 27 *Current Biology* 199 (Jan. 5, 2017).

¹⁶⁸ NIH Guidance, *Consideration of Sex as a Biological Variable in NIH-funded Research* at 1 (2017), https://orwh.od.nih.gov/sites/orwh/files/docs/NOT-OD-15-102_Guidance.pdf.

¹⁶⁹ Janine Austin Clayton (Office of Research on Women’s Health, NIH), “Applying the new SABV (sex as a biological variable) policy to research and clinical care,” *Physiology & Behavior* 187 (2018), 2.

¹⁷⁰ 81 FR 31467 (“Gender identity means an individual’s internal sense of gender” whose expression “may or may not conform to social stereotypes associated with a particular gender”); 81 FR 31468 (“[sex] stereotypes can include the expectation that individuals will consistently identify with only one gender and that they will act in conformity with the gender-related expressions stereotypically associated with that gender.”) (emphasis added).

¹⁷¹ Cf. 18 U.S.C. 249 (Shepard-Byrd Hate Crimes Act) (defining gender identity as “actual or perceived gender-related characteristics”).

¹⁷² See 84 FR 27855, n. 55, citing Daphne Stroumsa, Elizabeth F.S. Roberts, et al., “The Power and Limits of Classification—A 32 Year Old Man with Abdominal Pain,” *New England Journal of Medicine* (May 16, 2019), <https://www.ncbi.nlm.nih.gov/pubmed/31091369> (a patient with an electronic medical record classification as male did not receive care to treat “labor, placental abruption, or preeclampsia—urgent conditions presenting a potential emergency”).

it involved the actual death of an unborn child and attendant trauma and anguish for those involved, all potentially because of a misdiagnosis resulting from a reliance on stated gender identity as opposed to sex. Given that life-and-death decisions are frequently made in healthcare settings and often in urgent circumstances, this story serves as an example of the consequences that could result from the confusion caused by the 2016 Rule and its mandate to treat individuals “consistent with” stated gender identity.

Comment: Commenters stated that it is clear that characteristics traditionally protected under antidiscrimination law are those inherent, immutable, and readily identifiable. They stated that a binary and biological definition of sex enables consistency and clarity about who is a member of the protected category, what the prohibited conduct is, how covered entities must comply both by inaction and action, and when government enforces a right against discrimination. Commenters stated that changing the definition of the protected category to an identity that is changeable and fluid results in a legal standard that is impractical if not impossible to apply to particular circumstances. Commenters found that those courts that recognize gender identity discrimination apply the prohibitions inconsistently.

Healthcare providers submitted comments stating that “gender identity” is a subjective psychological concept that cannot be anatomically located within the brain, and that no MRI or CT scan, autopsy, genetic testing, blood test, or pathology report can localize an “internal sense” and verify whether the gender identity of a patient is actually male, female, neither, or a combination of male or female.

Commenters stated that they did not understand the categories in the 2016 Rule’s definition of gender identity which are not obviously limited in the number of possible permutations nor anchored in biology. Commenters were concerned that Title IX’s prohibitions against disparate treatment of biological women as different from biological males may no longer be prohibited or even enforceable. When a protected category that was binary now becomes a subjective spectrum, commenters did not know what the substantive standard was to establish a facial violation, or how to apply it to particular facts. Some commenters stated that it contradicts Title IX to treat sex as a non-binary concept when the statute explicitly protects persons of either “one sex” or “the other sex.” Commenters stated the

2016 Rule retained the words male or female—two categories which have long formed the biological and binary concept of sex—but eliminated their substantive content. The breadth of the definition of gender identity included both exterior (“expression”) and interior (“internal” sense) characteristics; mental (“identity”) and physical (“body characteristics”); variable over time (at birth vs. after birth), feminine or masculine (binary), both (“some combination”), and androgyny (“neither”). Commenters stated that they did not have clarity as to how to assess claims of “either/or” disparate treatment as well as “both/and.” Commenters also noted the text also included an expansive catchall provision stating that the definition of gender identity “is not limited to” what was in that enumerated list.

Response: The Department agrees that gender identity is difficult to define, in some cases difficult to categorize, and frequently very difficult to determine with objective certainty. For these and reasons stated elsewhere, the 2016 Rule’s provisions on gender identity were confusing facially and in application. This final rule eliminates that confusion by returning to the plain meaning of the underlying statutes, relying as it does on the plain meaning of “sex” as biologically binary.

Comment: The Department received comments stating that the proposed rule would harm the privacy interests of children with gender dysphoria who seek to use restrooms according to gender identity and would otherwise encourage bullying. Commenters also alleged that in Federal court cases concerning gender identity unrelated to health services, courts have rejected arguments about competing privacy concerns of non-transgender individuals with respect to bathroom access for transgender individuals.

Response: These comments show that, although the preamble to the 2016 Rule had stated that it was not intended to overrule “existing Federal, State and local laws, rules or regulations” such as Title IX or its regulations, under which “certain types of sex-specific facilities such as restrooms may be permitted” such as bathrooms or intimate facilities,¹⁷³ even the 2016 Rule’s supporters can reasonably interpret its provisions as doing precisely that.

The Department acknowledges that there is new and developing case law on the intersection of privacy concerns of non-transgender individuals and bathroom access for transgender

individuals.¹⁷⁴ As commenters pointed out, there have been recent Title IX complaints regarding access to intimate facilities and associated case law. One complaint alleged a sexual assault by a male who identifies as female and had been granted access to a single-sex (female) facility based on stated gender identity.¹⁷⁵ Another incident involved dueling discrimination and privacy complaints concerning the use of communal shower facilities. After filing a complaint, a male who identifies as female was granted an exception to live as a female. A group of females filed complaints that their privacy rights were violated.¹⁷⁶ At least one Title IX complaint similar to these was denied by a court because of the specific facts of the case.¹⁷⁷ But the case law on such complaints is very new and still developing.

The Department notes that, regardless of whether Title IX *requires* covered entities to maintain sex-specific bathrooms, the Title IX regulations continue to *permit* policies that regulate intimate facilities based on sex. These regulations are consistent both with the ordinary, biological understanding of the word “sex” as reflected throughout the text of Title IX and the ordinary understanding of discrimination. Indeed, as the U.S. government has noted, the provisions in Title IX stating that nothing in that statute prohibits educational institutions from “maintaining separate living facilities *for the different sexes*” “could not sensibly function if ‘the term ‘sex’ includes ‘gender identity,’ which, unlike ‘sex,’ may not be limited to two categories.”¹⁷⁸ Moreover, it has long been understood that, although “separate bathrooms are obviously not blind to sex, they do not discriminate because of sex . . . so long as they do not treat men or women disadvantageously compared to the opposite sex.”¹⁷⁹ In light of experience, including experience since the 2016 Rule was promulgated, the Department concludes that this final rule, by

¹⁷⁴ See, e.g., *Soule v. Conn. Ass’n of Schools*, No. 3:20-cv-00201 (D. Conn. filed Feb. 12, 2020).

¹⁷⁵ Moriah Balingit, “After Alleged Sexual Assault, Officials Open Investigation of Transgender Bathroom Policy,” *The Washington Post* (Oct. 9, 2018), https://www.washingtonpost.com/local/education/after-alleged-sexual-assault-officials-open-investigation-of-transgender-bathroom-policy/2018/10/09/431e7024-c7fd-11e8-9b1c-a90f1daae309_story.html.

¹⁷⁶ See Department of Defense, “Report and Recommendations,” 37.

¹⁷⁷ See *Doe v. Boyertown Area Sch. Dist.*, 897 F.3d 518, 531–33 (3d Cir. 2018).

¹⁷⁸ Statement of Interest for DOJ, *Soule v. Conn. Ass’n of Schools*, 3:20-cv-00201–RNC (D. Conn., filed March 27, 2020) at 5.

¹⁷⁹ Brief for EEOC, *Harris Funeral Homes*, at 36.

¹⁷³ 81 FR 31409.

removing the possibility that the Section 1557 regulations could be read as overruling Title IX's regulatory permission to maintain certain sex-segregated facilities (a permission consonant with Title IX's prohibition on sex discrimination, as explained above), will better permit covered entities to balance relevant privacy interests. The Department declines to retain a provision that could reasonably be read to prohibit covered entities from recognizing the difference between men and women or acting to protect men's and women's privacy interests in HHS-funded health programs or activities.¹⁸⁰

Comment: Some commenters challenged the requirement under the 2016 Rule that medical professionals must use a patient's preferred pronouns based entirely on self-identification, regardless of biological sex or the presence or absence of surgery or the use of masculinizing or feminizing hormone treatments. Some commenters disagreed with any requirement that forces providers to treat patients in a manner other than according to their biological sex, including through coerced use of pronouns. Others stated that social transition treatment required providers to use the preferred pronouns or preferred names of patients, and to identify patients according to their preferred sex effectively at all times.

Response: The 2016 Rule preamble held out a provider's "persistent and intentional refusal to use a transgender individual's preferred name and pronoun and insistence on using those corresponding to the individual's sex assigned at birth" as a potential example of hostile-environment sex discrimination under Section 1557.¹⁸¹ At least one district court has held similarly that when a provider allegedly "continuously referred to" a transgender patient "with female pronouns" in accordance with her sex, this could be sufficient grounds for a sex discrimination claim under Section 1557 in light of the *Price Waterhouse* "stereotyping" theory discussed above.¹⁸² This view, again, rested on a misreading of Title IX.

¹⁸⁰ See OCR Voluntary Resolution Agreement with The Brooklyn Hospital Center (requiring assignment of persons to shared patient rooms according to gender identity) (2015), sub-regulatory guidance contained therein since *abrogated*, as discussed above, <https://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/TBHC/vra.pdf>.

¹⁸¹ 81 FR 31406.

¹⁸² See *Prescott v. Rady Children's Hospital-San Diego*, 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017) ("As other courts have recognized, '[b]y definition, a transgender individual does not conform to the sex-based stereotypes of the sex that he or she was assigned at birth.' . . . The Complaint

Pronouns are not stereotypes. Pronouns reflect the most elementary sex-based classification in the English language. They are routinely used in scientific contexts to refer to humans as well as any other animals that are either male or female. They identify an individual's sex, which is an essential element of determining sex-based discrimination under Title IX. This final rule does not interfere with the medical judgment of any covered entity in treating gender dysphoria, but Title IX cannot be used to require covered entities to ignore or override the underlying distinctions of sex that Title IX itself is premised upon.

The Department thus does not believe that Title IX requires participants in covered entities to use a pronoun other than the one consistent with an individual's sex and does not believe it otherwise appropriate to dictate pronoun use or force covered entities to recognize a conception of sex or gender identity with which they disagree for medical, scientific, religious, and/or philosophical reasons. This final rule does not prevent covered entities from maintaining or adopting pronoun policies, or endorsing a variety of theories of gender identity, to the extent otherwise allowed by statutory and constitutional law. This rule also does not prevent State and local jurisdictions from imposing such policies to the extent allowed by statutory and constitutional law.

Comment: A commenter contended that the Department exceeded its authority by proposing to roll back protections for transgender individuals, noting that a 2012 letter from OCR stated that Section 1557 protections included gender identity.¹⁸³

Response: Consistent with the position taken by the Executive Branch on Title IX since 2017, the Department has concluded that the position stated in the 2012 OCR letter reflected an incorrect understanding of Title IX, as incorporated into Section 1557. The Department indefinitely suspended the sub-regulatory guidance contained in the 2012 letter in light of the proposed changes to the rule. 84 FR 27872 n.175. Having considered the matters raised fully, the Department disavows the

alleges that the RCHSD staff discriminated against Kyler by continuously referring to him with female pronouns, despite knowing that he was a transgender boy and that it would cause him severe distress. . . . Accordingly, Ms. Prescott's claim on behalf of Kyler survives under [Section 1557 of] the ACA.").

¹⁸³ See Letter from Leon Rodriguez, Director, U.S. Dep't of Health & Human Servs., Office for Civil Rights, to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights (Jul. 12, 2012), available at <https://perma.cc/RB8V-ACZU>.

views expressed in the 2012 letter that concern the coverage of gender identity and sex discrimination under Section 1557. Similarly, the Department disavows the views expressed in a voluntary resolution agreement entered into with The Brooklyn Hospital Center in 2015 resolving allegations of gender identity discrimination under Section 1557.¹⁸⁴ To the extent that those views were integrated or incorporated into the 2016 Rule with respect to gender identity, they are rescinded in this final rule.

Comment: Many commenters asserted that the proposed rule removes legal protections for transgender individuals and would allow or encourage providers to deny basic healthcare to individuals who identify as transgender. Commenters pointed to what they said were instances of discrimination on the basis of the identity of the patient as a transgender individual, where providers allegedly used excessive precautions, avoided touching the patient, engaged in unnecessary physical roughness in pelvic examinations, made insensitive jokes, intentionally concealed information about options for different treatments, asked unnecessarily personal questions, referred to transgender patients by pronouns and terms of address based on their biological sex rather than their gender identity, and/or disclosed a patient's medical history without authorization. Others cited 15 closed cases handled by OCR of alleged discrimination against transgender individuals in which providers had refused sex-specific care or coverage on the basis of discrepancies between the individual's sex and stated gender identity.

Response: The Department believes that all people should be treated with dignity and respect, regardless of their characteristics including their gender identity, and they should be given every protection afforded by the Constitution and the laws passed by Congress. The Department is committed to fully and vigorously enforcing all of the nondiscrimination statutes entrusted to it by Congress. For reasons explained above, the term "on the basis of . . . sex" in Section 1557 does not encompass discrimination on the basis of gender identity. Unprofessional conduct such as inappropriate jokes or questions, excessive precautions, or concealment of treatment options, may be covered under State medical malpractice, tort, or battery laws.

Commenters' concern about denial of basic healthcare to transgender

¹⁸⁴ See OCR Voluntary Resolution Agreement with The Brooklyn Hospital Center.

individuals appears to be based largely on unsubstantiated hypothetical scenarios. Although some rare instances have been reported, they are not recent, and the Department is unaware of a significant number of cases where a transgender individual who has accurately identified his or her (biological) sex to a provider has nonetheless been denied relevant, non-transition-related healthcare on the basis of his or her gender identity. The Department is not aware of any providers claiming that they see a need for or wish to make broad, identity-based denials of care. To the contrary, many providers who specifically object to the 2016 Rule's mandates with respect to sex-reassignment treatments and/or elective abortion procedures explicitly affirmed in comments their commitment to treat all patients without regard to self-identification, inclusive of gender identity or sexual orientation. In the anecdotes of discrimination reported by commenters, what is often being alleged is poor care or insensitive treatment rather than outright denial of care, and is often lacking documentation. This lack of substantial evidence supports the Department's understanding, in contrast to the allegations of some commenters, that denial of basic healthcare on the basis of gender identity is not a widespread problem in the U.S. Moreover, to the extent that the 2016 Rule provided against denial of basic healthcare on the basis of gender identity, those provisions of the rule have been preliminarily enjoined since December 2016 and have since been vacated; any future mistreatment hypothesized by commenters would not, then, be the result of this final rule.

Additionally, several of the behaviors alleged by commenters would be unlawful even if Title IX and Section 1557 had never been enacted. Unnecessary roughness in a pelvic examination, or any other medical procedure or examination without a medical basis or appropriate informed consent, may be a case of battery or malpractice, which should be reported to local law enforcement and/or licensing authorities. If such conduct willfully causes bodily injury because of gender identity, and is in or affecting interstate commerce, then it could be a Federal hate crime.¹⁸⁵ When OCR becomes aware of any crimes that may violate Federal law, it may be required to make a referral to the Department of

Justice.¹⁸⁶ The Emergency Medical Treatment and Labor Act (EMTALA) also requires stabilization in certain emergency medical situations.

OCR also continues to enforce Federal health information privacy laws to ensure the confidentiality of all individuals' protected medical information, including information concerning gender dysphoria diagnosis or treatment, sexual orientation, or HIV status.¹⁸⁷

The Department, through its Offices of Minority Health, supports outreach to diverse populations and those facing particularized or disproportionate health challenges.

Comment: Commenters alleged that removing the definitions of "gender identity" and "on the basis of sex" (which includes gender identity) from the rule would "erase" transgender individuals from the *Code of Federal Regulations*.

Response: The Department denies that removal of definitional terms in one regulation has the wide-ranging impact that commenters allege. Under this final rule, transgender individuals remain protected by the same civil rights laws as any other individual, and the Department will vigorously enforce their statutory and regulatory civil rights. This final rule also does not and cannot erase explicit statutory protections for individuals on the basis of gender identity, such as in hate crimes laws that bar violence committed on the basis of an individual's gender identity.¹⁸⁸

iii. Termination of Pregnancy

Comment: Commenters reacted to the proposed rule's elimination of the 2016

Rule's language that had encompassed "termination of pregnancy" within the definition of "on the basis of sex." Commenters stated that the Department's declining to take a position about the full scope of the meaning of "termination of pregnancy" in the 2019 NPRM was confusing, and that the point merited clarification. Some providers objected to the inclusion of "termination of pregnancy" under the 2016 Rule to the extent that it referred to elective abortions. Other providers interpreted "termination of pregnancy" to mean both elective abortion and natural termination of pregnancies. Others stated that all forms of termination of pregnancy should be encompassed in the prohibition on discrimination on the basis of sex.

Some commenters stated that removing the 2016 Rule's definition of "on the basis of sex" will allow discrimination against women based upon their abortion history. Commenters also identified a variety of other women's healthcare services related to pregnancy that may be implicated, including prenatal and postpartum services, tubal ligations, and birth control (both as a contraceptive and when used to treat other medical conditions). They also referred to infertility treatments including in vitro fertilization, and pointed to *Benitez v. North Coast Women's Care Medical Group, Inc.*¹⁸⁹ as a real-world example of discrimination in this regard. Commenters said that the proposed rule would or could permit discrimination against women through denial or restriction of access to treatments such as these, as well as treatments prior to, during, or after a miscarriage.

Response: Under this final rule, the Department will interpret Section 1557's prohibition on sex-based discrimination consistent with Title IX and its implementing regulations. This final rule ensures that the Department's Section 1557 regulations are implemented consistent with the abortion neutrality and statutory exemptions in Title IX. The regulations are subject to the text of the Title IX statute, so they cannot be "construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion." 20 U.S.C. 1688. As explained below, this final rule also incorporates that statutory text explicitly into the Title IX regulations for the sake of clarity, to ensure those regulations are

¹⁸⁵ 18 U.S.C. 249(c)(4) (prohibiting hate crimes that are based on "actual or perceived religion, national origin, gender, sexual orientation, gender identity, or disability").

¹⁸⁶ See 34 U.S.C. 41303 ("All departments and agencies within the Federal government . . . shall report details about crime within their respective jurisdiction to the Attorney General"); 28 U.S.C. 535(b) ("any information, allegation, or complaint received in a department or agency of the executive branch of government relating to violations of title 28 involving Government officers and employees shall be expeditiously reported to the Attorney General by the head of the department or agency").

¹⁸⁷ See U.S. Department of Health and Human Services, "Careless handling of HIV information jeopardizes patient's privacy, costs entity \$387k" (May 23, 2017), available at <https://www.hhs.gov/about/news/2017/05/23/careless-handling-hiv-information-costs-entity.html> (OCR enforcement under HIPAA); see also U.S. Department of Health and Human Services, "HHS Office for Civil Rights Secures Corrective Action and Ensures Florida Orthopedic Practice Protects Patients with HIV from Discrimination" (Oct. 30, 2019), <https://www.hhs.gov/about/news/2019/10/30/hhs-ocr-secures-corrective-action-and-ensures-fl-orthopedic-practice-protects-patients-with-hiv-from-discrimination.html> (OCR enforcement under Section 504 and Section 1557).

¹⁸⁸ See 18 U.S.C. 249(c)(4) (prohibiting hate crimes that are based on "actual or perceived religion, national origin, gender, sexual orientation, gender identity, or disability").

¹⁸⁹ *Benitez v. N. Coast Women's Care Med. Grp., Inc.*, 106 Cal. App. 4th 978 (Mar. 4, 2003).

implemented consistent with the statute.

The *Franciscan Alliance* court vacated the “termination of pregnancy” language in the 2016 Rule because it failed to incorporate the abortion-neutrality language from the Title IX statute.¹⁹⁰ The Court held that “Congress intended to incorporate the entire statutory structure, including the abortion and religious exemptions,”¹⁹¹ and concluded that by failing to include these exemptions, the Department unlawfully “expanded the ‘ground prohibited under’ Title IX that Section 1557 explicitly incorporated.”¹⁹²

The Department is committed to enforcing vigorously the prohibition on discrimination on the basis of sex, through its implementing regulations (which include provisions on termination of pregnancy), as interpreted consistent with the text of Title IX. OCR will fully enforce its statutory authorities concerning any discriminatory denial of access to women’s health services, including those related to pregnancy. The Department, however, declines to speculate on particular hypotheticals related to termination of pregnancy, and will proceed based on the specific facts and circumstances of each case that may arise.

Comment: Some commenters stated that without the 2016 Rule, there would be serious and/or life-threatening results because hospitals would not provide abortion care on the basis of religious beliefs, referencing *ACLU v. Trinity Health Corporation*, 178 F. Supp. 3d 614 (E.D. Mich. 2016), and *Means v. U.S. Conference of Catholic Bishops*, No. 1:15–CV–353, 2015 WL 3970046 (W.D. Mich. 2015). Some alleged that the proposed rule does not comply with constitutional law regarding abortion or the applicable standard of scrutiny for sex discrimination and imposes undue burdens on women. Some stated that the proposed rule would hurt women’s health by denying or encouraging denial of access to abortion.

¹⁹⁰ *Franciscan Alliance*, 227 F. Supp. 3d 660, 690–91 (N.D. Tex. 2016) (“Title IX prohibits discrimination on the basis of sex, but . . . categorically exempts any application that would require a covered entity to provide abortion or abortion-related services. 20 U.S.C. 1688. . . . Failure to incorporate Title IX’s religious and abortion exemptions nullifies Congress’s specific direction to prohibit only the ground proscribed by Title IX. That is not permitted.”); *Franciscan Alliance*, 414 F. Supp. 3d 928, 945, 947 (N.D. Tex. 2019) (adopting reasoning from preliminary injunction and vacating the portions of the rule it deemed unlawful).

¹⁹¹ *Franciscan Alliance*, 227 F. Supp. 3d at 690–91.

¹⁹² *Id.* (citing *Corley v. U.S.*, 556 U.S. 303, 314 (2009)).

Others submitted evidence challenging the idea that the termination of pregnancy provision, if retained (and not enjoined by a court), would materially increase abortion access for the average person. Specifically, they state that the overwhelming majority of abortions in America are performed at high-volume abortion clinics, and that there is no reason to suspect that retaining the 2016 Rule would lead to a significant increase in hospitals or other institutions willing to perform abortions when compared to abortion providers as a whole. According to commenters, this is in part because many hospitals and medical institutions that do not have a formal position objecting to abortion are free to engage in them now yet do not perform them or do so only to a limited extent.¹⁹³ Additionally, commenters said that the relative dearth of doctors willing to perform abortions at institutions appears largely to be a result of independent physician choices, not of the policies of institutions that object to abortions.

Some commenters were concerned that the 2016 Rule’s provisions on termination of pregnancy devalue human life, both with respect to unborn children who lose their lives, and with respect to mothers, as many abortions are dangerous and lead to life-threatening complications for women. Other commenters stated that HHS has a compelling interest in defending the sanctity of innocent human life at all stages. Some institutional providers who object to abortion stated that they can and do treat women who have had miscarriages, even using techniques that are commonly used in abortion (such as dilation and curettage), so long as the procedure itself is not intended to and does not result in the taking of a human life.

Response: The Department appreciates all comments related to the highly controversial matter of abortion. The strong views that Americans hold on various sides of this question are an important policy reason supporting the Congressionally-enacted abortion-neutrality language in Federal statutes

¹⁹³ As one commenter wrote, “A 2018 study in the journal *Contraception* found that only 7% of obstetrician-gynecologists in private practice had performed an abortion in 2013 or 2014. An older study published in 2011 in *Obstetrics and Gynecology* found that 97% of practicing obstetrician-gynecologists encountered patients seeking an abortion, though only 14% performed them. Finally, a 2014 study published in *Perspectives on Sexual and Reproductive Health* found that just 5% of abortions take place in hospitals or physicians’ offices, demonstrating that the vast majority of abortions are not performed by healthcare providers at hospitals or physicians’ offices.”

such as Title IX. Because Section 1557 expressly incorporated Title IX—therefore including the abortion-neutrality provision—the Department likewise incorporates that provision for purposes of the covered entities under Section 1557. This final rule also does not add any abortion-related conscience protections beyond those that Congress has set down in statute. Those statutes have not been held to be unconstitutional. The Department will vigorously enforce these and all other Federal civil rights statutes under its jurisdiction.

This final rule also does not abrogate other longstanding Federal laws that may apply to situations related to pregnancy, including EMTALA and the Pregnancy Nondiscrimination Act. The Department will read all applicable laws and exemptions harmoniously.¹⁹⁴ In addition, the termination of pregnancy provisions of the 2016 Rule have been enjoined since December 2016 and are now vacated. Finally, this rule does not change the legal ability of providers to offer abortions. The Department therefore disagrees with commenters who predict that the finalization of this rule will significantly reduce abortion access or cause resulting health consequences.

iv. Sexual Orientation

Comment: Some commenters stated that the 2016 Rule’s § 92.209 should be removed because Title VII and Title IX do not include sexual orientation in their prohibition of sex discrimination. They used as an example the fact that the previous Administration treated sex, sexual orientation, and gender identity as different concepts in an executive order that prohibited discrimination on the basis of sex, sexual orientation, and gender identity in Federal hiring, contracting, and employment.¹⁹⁵ They added that Congress has rejected the sexual orientation and gender identity provisions in the Employment Non-Discrimination Act, the Equality Act, and the Student Non-Discrimination Act.

Others said that sexual orientation is a foundational trait of an individual and that cannot be separated and/or isolated from his or her being and that the proposed rule would enable discrimination based on sexual orientation. Other commenters cite a general fear of discrimination; abuse or neglect related to sexual orientation; a

¹⁹⁴ See 42 U.S.C. 13955dd(c)(1)(ii) (EMTALA); Public Law 95–555, 92 Stat. 2076 (Oct. 31, 1978) (Pregnancy Nondiscrimination Act).

¹⁹⁵ Exec. Order No. 13672, 79 FR 42971–72 (July 21, 2014), <https://www.govinfo.gov/content/pkg/FR-2014-07-23/pdf/2014-17522.pdf>.

lack of inclusive services; social isolation; a sense of invisibility; lack of educated providers; and distrust of the healthcare system. They argue that these burdens lead to inadequate care, including preventive care, and require a Federal response. In support of these claims, commenters cited a survey stating that 8% of lesbian, gay, and bisexual respondents allege they have been refused care from a healthcare provider due to their sexual orientation.¹⁹⁶ Other commenters, however, cited a survey showing that 97% of responding faith-based medical professionals attest that they “care for all patients in need, regardless of sexual orientation, gender identification, or family makeup, with sensitivity and compassion, even when [they] cannot validate their choices.”¹⁹⁷ Thus, some commenters argue, the issue is not one of refusing to care for certain patients based on identity, but instead a matter of declining to participate in a discrete set of morally controversial procedures and treatments that are available elsewhere.

Others said that discrimination because of an individual’s sexual orientation is plainly a species of sex stereotyping that is impermissible under Section 1557’s sex discrimination prohibition and cite *Baldwin v. Foxx*, an EEOC decision,¹⁹⁸ in support of the idea that the final rule should cover sexual orientation.

Response: OCR may only enforce laws that Congress has enacted and the regulations that were promulgated pursuant to that statutory authority. The plain meaning of “sex” under Title IX encompasses neither sexual orientation nor gender identity. Concerning commenters’ discussion of Congress’s failure to add sexual orientation and gender identity to contexts encompassed by Title IX or Title VII, the Department is guided primarily by its understanding of the plain meaning of the statute.¹⁹⁹ This final rule does not change the status quo with respect to sexual orientation, because, as the Department stated in the 2019 NPRM

preamble, sexual orientation was not explicitly included in the 2016 Rule text,²⁰⁰ and the Department has concluded that it is a category separate from sex and does not fall within the ambit of discrimination “on the basis of sex.”

The U.S. Attorney General and Solicitor General have persuasively argued that *Price Waterhouse* does not elevate sexual orientation to a protected category using a sex stereotyping theory under Title VII, just as it fails to make gender identity a protected category under Title IX.²⁰¹ Much as the reasonable distinctions on the basis of sex discussed above (in the subsection on gender identity) are not illegitimate sex stereotypes, so too, distinctions on the basis of sexual orientation do not as such constitute sex stereotyping. As an initial matter, distinctions on the basis of sexual orientation may be sex-neutral and apply equally to both sexes, which would mean that they do not burden anyone on the basis of sex. The Eleventh Circuit has recently rejected the application of *Price Waterhouse* to expand “sex” to include “sexual orientation,” citing an abundance of case law in support.²⁰² Additionally, as

the Solicitor General has argued, distinctions made on the basis of sexual orientation are not necessarily based on stereotypes, as they may instead be based on “moral or religious beliefs about sexual, marital, and familial relationships.”²⁰³ “There is nothing irrational or improper” in such beliefs.²⁰⁴

The Department notes that in *Baldwin v. Foxx*, the EEOC reversed its long-held position that sexual orientation discrimination was not protected under Title VII.²⁰⁵ The United States government has since rejected the

discrimination based on sexual orientation.”); *Wrightson v. Pizza Hut of Am.*, 99 F.3d 138, 143 (4th Cir. 1996), abrogated on other grounds by *Oncale v. Sundowner Offshore Servs.*, 523 U.S. 75, 118 S. Ct. 998, 140 L.Ed.2d 201 (1998) (“Title VII does not afford a cause of action for discrimination based upon sexual orientation. . . .”); *Vickers v. Fairfield Med. Ctr.*, 453 F.3d 757, 762 (6th Cir. 2006) (“[S]exual orientation is not a prohibited basis for discriminatory acts under Title VII.”); *Hamner v. St. Vincent Hosp. & Health Care Ctr., Inc.*, 224 F.3d 701, 704 (7th Cir. 2000) (“[H]arassment based solely upon a person’s sexual preference or orientation (and not on one’s sex) is not an unlawful employment practice under Title VII.”); *Williamson v. A.G. Edwards & Sons, Inc.*, 876 F.2d 69, 70 (8th Cir. 1989) (“Title VII does not prohibit discrimination against homosexuals.”); *Rene v. MGM Grand Hotel, Inc.*, 305 F.3d 1061, 1063–64 (9th Cir. 2002) (“[A]n employee’s sexual orientation is irrelevant for purposes of Title VII. It neither provides nor precludes a cause of action for sexual harassment. That the harasser is, or may be, motivated by hostility based on sexual orientation is similarly irrelevant, and neither provides nor precludes a cause of action.”); *Medina v. Income Support Div.*, 413 F.3d 1131, 1135 (10th Cir. 2005) (“Title VII’s protections, however, do not extend to harassment due to a person’s sexuality. . . . Congress has repeatedly rejected legislation that would have extended Title VII to cover sexual orientation.”) (internal quotations omitted). *Evans* and the EEOC question these decisions, in part, because of *Price Waterhouse* and *Oncale*. Whether those Supreme Court cases impact other circuit’s decisions, many of which were decided after *Price Waterhouse* and *Oncale*, does not change our analysis that *Blum* is binding precedent that has not been overruled by a clearly contrary opinion of the Supreme Court or of this Court sitting *en banc*.”).

²⁰³ *Bostock v. Clayton Cty. Bd. of Commissioners*, 2019 WL 4014070 at *25 (U.S. 2019) (Brief for the United States as *Amicus Curiae* Supporting Affirmance in No. 17–1618 (*Bostock v. Clayton Cty. Bd. of Commissioners*) and Reversal in No. 17–1623 (*Altitude Express Inc. v. Zarda*)).

²⁰⁴ See Tuan Anh Nguyen v. *INS*, 533 U.S. 68. See also *Obergefell v. Hodges*, 135 S. Ct. 2585, 2602 (2015) (referring to opinions that are “based on decent and honorable religious or philosophical premises” and are therefore not “disparaged here”); See *Masterpiece Cakeshop v. Colorado Civil Rights Comm’n*, 138 S. Ct. 1719, 1729 (2018) (“To describe a man’s faith as ‘one of the most despicable pieces of rhetoric that people can use’ is to disparage his religion in at least two distinct ways: by describing it as despicable, and also by characterizing it as merely rhetorical—something insubstantial and even insincere.”).

²⁰⁵ See e.g., *Angle v. Veneman*, EEOC Decision No. 01A32644, 2004 WL 764265, at *2 (Apr. 5, 2004) (recognizing that the EEOC had “consistently held that discrimination based on sexual orientation is not actionable under Title VII”), *Marucci v. Caldera*, EEOC Decision No. 01982644, 2000 WL 1637387, at *2–*3 (Oct. 27, 2000).

²⁰⁰ 81 FR 31390 (“OCR has decided not to resolve in this rule whether discrimination on the basis of an individual’s sexual orientation status alone is a form of sex discrimination.”).

²⁰¹ See *Bostock v. Clayton Cty. Bd. of Commissioners*, 2019 WL 4014070 at *26 (U.S. 2019) (Brief for the United States as *Amicus Curiae* Supporting Affirmance in No. 17–1618 (*Bostock v. Clayton Cty. Bd. of Commissioners*) and Reversal in No. 17–1623 (*Altitude Express Inc. v. Zarda*)) (“Title VII prohibits disparate treatment of men and women regardless of sexual orientation. Gay, lesbian, and bisexual employees, no less than straight employees, may invoke *Price Waterhouse* if they are subjected to gender-based stereotypes; a gay man who is fired for being too effeminate has just as strong a claim as a straight man who is fired for that reason.”). See also *Etstitt v. Utah Transit Authority*, 502 F.3d 1215, 1224–25 (10th Cir. 2007) (explaining that the legal issue “is whether members of one sex are exposed to disadvantageous terms or conditions of employment to which members of the other sex are not exposed”).

²⁰² *Evans v. Georgia Reg’l Hosp.*, 850 F.3d 1248, 1256–57 (11th Cir. 2017) (“*Price Waterhouse* and *Oncale* are neither clearly on point nor contrary to *Blum* [v. *Gulf Oil Corp.*, 597 F.2d 936 (5th Cir. 1979)] (“Discharge for homosexuality is not prohibited by Title VII. . . .”). These Supreme Court decisions do not squarely address whether sexual orientation discrimination is prohibited by Title VII.”) *Id.* at 1256–57 (“Finally, even though they disagree with the decisions, [the plaintiffs] acknowledge that other circuits have held that sexual orientation discrimination is not actionable under Title VII. See, e.g., *Higgins v. New Balance Athletic Shoe, Inc.*, 194 F.3d 252, 259 (1st Cir. 1999) (“Title VII does not proscribe harassment simply because of sexual orientation.”); *Simonton v. Runyon*, 232 F.3d 33, 36 (2d Cir. 2000) (“Simonton has alleged that he was discriminated against not because he was a man, but because of his sexual orientation. Such a claim remains non-cognizable under Title VII.”); *Bibby v. Phila. Coca Cola Bottling Co.*, 260 F.3d 257, 261 (3d Cir. 2001) (“Title VII does not prohibit

¹⁹⁶ See Shabab Ahmed Mirza and Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care, *Center for American Progress* (January 18, 2018), <https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/>.

¹⁹⁷ See Freedom2Care, “Conscience in healthcare: 2019,” <https://www.freedom2care.org/polling>.

¹⁹⁸ *Baldwin v. Foxx*, EEOC Appeal No. 0120133080, 2015 WL 4397641 (July 15, 2015).

¹⁹⁹ The Department agrees that Congressional inaction on this issue is supportive of the conclusion that Title IX does not encompass sexual orientation or gender identity, although it does not rely on this Congressional inaction in interpreting Title IX.

EEOC's novel position.²⁰⁶ Given Congress's decision not to extend civil rights protections on the basis of sexual orientation in the field of health and human services, the Department believes that State and local governments are best equipped to balance the multiple competing considerations involved in what remain a contentious and fraught set of questions.

v. Scrutiny for Sex-Based Classifications (Repeal of § 92.101(b)(3)(iv) of the 2016 Rule)

The Department proposed to repeal 92.101(b)(3)(iv) of the 2016 Rule, which forbids covered entities from operating a health program or activity restricted to members of one sex unless they can "demonstrate an exceedingly persuasive justification, that is, that the sex-specific health program or activity is substantially related to the achievement of an important health-related or scientific objective."²⁰⁷

Comment: Commenters stated that the 2016 Rule's provisions would pose an unjustified burden on, and lead to excessive scrutiny of, entities operating single-sex facilities in healthcare, as well as entities or persons who would claim religious or abortion exemptions under Title IX.

Response: The Department agrees that the 2016 Rule placed an unjustified burden on sex-specific health programs and activities conducted by private entities. The "exceedingly persuasive justification" legal standard under Equal Protection jurisprudence sets a limit to *governmental* actions that discriminate on the basis of sex, such as the military draft.²⁰⁸ This standard is foreign to Title IX jurisprudence.²⁰⁹ The 2016 Rule cited no case law in support of its decision to import a significantly modified version of this standard from constitutional law into its interpretation of "on the basis of sex" as defined by Title IX.²¹⁰ The express statutory exemptions to Title IX's nondiscrimination provisions, such as for fraternities and sororities, do not require individual covered entities to provide an "exceedingly persuasive justification" before being able to benefit from the exemption. Title IX also

does not require religious entities to provide such a justification to qualify for the religious exemption from Title IX nondiscrimination provisions. To require such a justification in the enforcement of Section 1557 would be to impose a significant burden on private entities that the statutory text does not contemplate. Government actors are routinely subjected to levels of judicial scrutiny that private parties (even private parties receiving Federal funds) are not, such as where constitutional provisions restrict government action, or where statutes allow civil rights actions against State actors. *See, e.g.,* 1st Am., U.S. Const.; 42 U.S.C. 1983; 42 U.S.C. 2000bb, *et seq.* It would be inappropriate to constrain medical professionals' best judgment by requiring them to meet the governmental burden of proof every time they seek to draw a reasonable distinction on the basis of sex in providing healthcare or separate programs or activities for the two sexes.²¹¹ As stated above, such distinctions are not inherently discriminatory: It is not discriminating against men to exclude them from, for example, gynecological services, because men are not similarly situated to women for purposes of such services. Providers accordingly should not be required to present an "exceedingly persuasive justification" for providing gynecological services only to women. OCR will, however, evaluate, and respond appropriately to, any allegations that a covered entity's sex-specific health programs or activities have in fact discriminated unlawfully on the basis of sex, including sexual harassment.²¹²

vi. Disparate Impact Under § 92.101(b)(3)(iii) of the 2016 Rule

The Department proposed to repeal 92.101(b)(iii) of the 2016 Rule, which prohibited selection of sites or facilities that have an effect of discriminating on the basis of sex.²¹³

Comment: Some commenters opposed repealing language that affirmed a disparate impact theory under grounds of nondiscrimination encompassed by Section 1557, contending that the civil

rights statutes cited in Section 1557 authorize disparate impact claims.

One commenter asserted that the very existence of Section 1557 indicates that the ACA intends to extend protections against disparate impact discrimination to private rights of action: Title VI already applied in the context of healthcare programs and activities, so Section 1557 would have been meaningless if it did not also allow for private rights of action for disparate impact discrimination. The same commenter also took issue with the proposed rule's elimination of monetary damages for disparate impact claims.

Response: Case law has indicated that certain civil rights statutes incorporated by Section 1557 do authorize disparate impact claims: Namely, claims with respect to discrimination on the basis of race, color, national origin, and disability.²¹⁴ Title IX, however, authorizes no such claims regarding discrimination on the basis of sex. Similarly, provisions relating to site or facility selection based on race, color, national origin, or disability are found in HHS's Title VI and Section 504 regulations, but are not found in HHS's Title IX regulations.²¹⁵ Insofar as the 2016 Rule added new grounds of prohibited discrimination not found in the statute, the Department believes it is necessary to revert to the underlying statutes and their implementing regulations. As a result, to the extent any of the underlying statutes authorize disparate impact claims, this final rule will recognize such claims by virtue of its reliance on the governing statutes, regulations, guidance and case law applicable to such claims, without needing to delineate the availability or lack of availability of all possible claims in this final rule. In reviewing all complaints that raise a disparate impact claim, the Department will consider the circumstances of each complaint and will independently apply each statute and underlying regulation, according to its text and any applicable court precedents, to the health context under Section 1557.²¹⁶

Comment: Some commenters stated that that the proposed rule's removal of protections against disparate impact discrimination, especially concerning race, color, and national origin, will lead to more instances of discrimination and fewer means of recourse.

²⁰⁶ See Brief for United States, *Bostock v. Clayton Cty. Bd. of Commissioners*, No. 17–1618 (U.S. filed Aug. 23, 2019).

²⁰⁷ 81 FR 31470.

²⁰⁸ See *Rostker v. Goldberg*, 453 U.S. 57, 69–70 (1981).

²⁰⁹ See, e.g., the clear distinction at *Whitaker v. Kenosha Unified Sch. Dist.*, 858 F.3d 1034, 1046–50 (7th Cir. 2017) ("Title IX Claim"), and 1050–54 ("Equal Protection Claim," encompassing the "exceedingly persuasive justification" test).

²¹⁰ Cf. 81 FR 31408–09.

²¹¹ See 2016 Rule, 81 FR 31409 ("In all cases, . . . OCR will expect a covered entity to supply objective evidence, and empirical data if available, to justify the need to restrict participation in the program to only one sex.").

²¹² See U.S. Department of Health and Human Services, "HHS OCR Secures Agreement with MSU to Resolve Investigation into Sexual Abuse by Larry Nassar" (2019), <https://www.hhs.gov/about/news/2019/08/12/hhs-ocr-secures-agreement-msu-resolve-investigation-sexual-abuse-larry-nassar.html>.

²¹³ 81 FR 31470.

²¹⁴ See 45 CFR 84.4(b)(4) (Title VI); 80.3(b)(2) (Section 504).

²¹⁵ See 45 CFR 80.3(b)(3) (Title VI); 84.4(b)(5) (Section 504).

²¹⁶ The Department responds to comments on private rights of action and damages below in the section on the enforcement mechanisms of the 2016 Rule.

Commenters cited data about health disparities in LGBT and female populations that they asserted were caused by discrimination on the basis of gender identity or termination of pregnancy, and stated that disparate impact analysis under the 2016 Rule is the appropriate way to address such discrimination. Another commenter questioned the persuasiveness of assessing the relative proportion of health disparities between racial, transgender, and/or female populations and other populations. The commenter stated that the available data did not provide conclusive evidence that the health disparities were caused by discriminatory conduct against LGBT persons and individuals seeking abortions, because correlations are not definite evidence of causation. The commenter contended that the proposed rule's approach causes ambiguity by blurring the distinctions between the two.

Response: As an initial matter, the Department wishes to reiterate that it will enforce Section 1557 in light of its regulations that already protect against disparate impact on the basis of race, color, or national origin. With respect to concerns regarding disparate impact on LGBT and abortion-seeking populations, the Department notes that this final rule conforms the Section 1557 Rule to HHS's Title IX regulations, under which the disparate impact standard does not apply. This conformity provides a clearer standard for covered entities, which are no longer required to have legally sufficient knowledge of the causes of statistically disproportionate health disparities on the basis of sex or gender identity.

vii. Insurance Coverage in § 92.207 of the 2016 Rule

The 2016 Rule prohibited insurers from “hav[ing] or implement[ing] a categorical coverage exclusion or limitation for all health services related to gender transition.”²¹⁷ Its preamble explained that this encompasses a “range of transition-related services” to treat gender dysphoria that are “not limited to surgical treatments and may include, but [are] not limited to, services such as hormone therapy and psychotherapy, which may occur over the lifetime of the individual,” and that may be required even if not “strictly identified as medically necessary or appropriate” insofar as the entity covers other types of similarly “elective” procedures.²¹⁸

Comment: Commenters indicated support for the 2016 Rule's insurance coverage requirements, claiming that the Rule has led to increased access to gender transition services for transgender patients, and that these services will be lost if the proposed rule is finalized. In comments, clinicians provided information about the specific procedures, services, or treatments they perform or offer with respect to gender identity. Among those who offer medical interventions under the category of “gender transition,” there was a consensus that such interventions included genital sex reassignment surgeries, cross-sex hormonal treatment, counseling, and often psychological or psychiatric support. Some clinicians stated that only patients with longstanding identification as the opposite sex and distress with their biological sex sought these services. Beyond these, some (but not all) clinicians indicated that gender transition procedures could also include surgery for feminization or masculinization of the entire body, which could include reduction, augmentation, removal, or transplant of tissue, skin, hair, or body fat, as well as “social transition” services such as voice training.²¹⁹

Some commenters regard transition services (which they said may include counseling, hormone therapy, and/or a variety of possible surgical treatments) as the governing standard of care. They directed the Department to studies on the matter including those cited in the 2016 Rule preamble, and cited what they said is a consensus of major American medical associations²²⁰ about sex-reassignment surgery, cross-sex hormones, and affirmation counseling.

²¹⁹ Examples of procedures identified were rhinoplasty, blepharoplasty, septoplasty, rhytidoplasty, abdominoplasty, electrolysis, liposuction, jawline modifications, scalp advancement, cheek and chin contouring, fat transfer, pectoral implants, forehead or brow lifts, or breast, buttocks, breast, waist, or lip augmentation/reduction. See Whitman-Walker Health; Philadelphia Transgender Center. HHS–OCR–2019–0007–138335 (Whitman-Walker Health). <http://www.thetransgendercenter.com/index.php/femaletomale1/ftm-price-list.html>; <http://www.thetransgendercenter.com/index.php/maletofemal1/mtf-price-list.html>.

²²⁰ Commenters cited Jason Rafferty, “Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents,” 142 *Pediatrics* no. 4 (Oct. 2018) (American Academy of Pediatrics policy statement), and noted that the American Medical Association, the American College of Physicians, the American Psychological Association, the American Psychiatric Association, the American Academy of Family Physicians, the Endocrine Society, the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics, among others, support transition-related treatments.

Commenters urged the Department to follow the 2016 Rule in relying on the standards promulgated by the World Professional Association for Transgender Health (WPATH).²²¹

Commenters stated that, under the WPATH standards and other protocols, treatment for gender dysphoria may require transition-related care.²²² Commenters asserted specific benefits from transition-related care in treating gender dysphoria.²²³ For example, commenters said that access to transition services leads to decreased health disparities, such as lower levels of depression and suicide attempts.²²⁴

With respect to adolescents, some commenters promoted approaches that affirm or encourage gender identity variation, including sex reassignment, citing data that they said showed it resulted in fewer mental health concerns.²²⁵ Some medical professionals also stated in comments that hormone blockers are a safe and reversible way to delay puberty, noting

²²¹ See 81 FR 31429.

²²² Commenters cited, for example, Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 *The Journal of Clinical Endocrinology & Metabolism* 3869 (2017); Am. Medical Ass'n, *AMA Policies on GLBT Issues, Patient-Centered Policy H-185.950, Removing Financial Barriers to Care for Transgender Patients* (2008), <http://www.imatyfa.org/assets/ama122.pdf>; and Am. Psychiatric Ass'n, *Position Statement on Discrimination Against Transgender and Gender Variant Individuals* (2012); http://www.dhcs.ca.gov/services/MH/Documents/2013_04_AC_06d_APA_ps2012_Transgen_Disc.pdf (citing WPATH Standards); Am. Psychological Ass'n, *Policy on Transgender, Gender Identity & Gender Expression Non-Discrimination* (2008), <http://www.apa.org/about/policy/transgender.aspx>.

²²³ Commenters cited, for example, Ashli A. Owen-Smith, et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals*, *J. Sexual Medicine* (Jan. 17, 2018); Gemma L. Witcomb et al., *Levels of Depression in Transgender People and its Predictors: Results of a Large Matched Control Study with Transgender People Accessing Clinical Services*, *J. Affective Disorders* (Feb. 2018); and Cecilia Dhejne et al., *Mental Health and Gender Dysphoria: A Review of the Literature*, 28 *Int'l Rev. Psychiatry* 44 (2016).

²²⁴ Commenters cited, for example, Lily Durwood, Katie A. McLaughlin, & Kristina R. Olson, *Mental Health and Self-Worth in Socially Transitioned Transgender Youth*, 56 *J. Am. Acad. Child Adoles. Psychiatry* 116 (2017); Kristina R. Olson et al., *Mental Health of Transgender Children Who Are Supported in Their Identities*, 137 *Pediatrics* (2016); and Stephen T. Russel et al., *Chosen Name Use Is Linked to Reduced Depressive Symptoms, Suicidal Ideation, and Suicidal Behaviors Among Transgender Youth*, 64 *J. Adolescent Health* 503 (2018), [https://www.jahonline.org/article/S1054-139X\(18\)30085-5/fulltext](https://www.jahonline.org/article/S1054-139X(18)30085-5/fulltext).

²²⁵ Commenters cited Hill DB, Menvielle E, Sica KM, Johnson A. *An affirmative intervention for families with gender variant children: parental ratings of child mental health and gender*. *J Sex Marital Ther.* 36(1):6–23 (2010).

²¹⁷ 81 FR 31472, 31435–36.

²¹⁸ *Id.*

they have been used historically for children experiencing precocious puberty, or puberty at a younger age.

Other commenters disagreed as to whether sex reassignment treatments or surgeries, or gender-affirming therapies, are the proper care for gender dysphoria, or even whether they are ever medically indicated. Instead of surgery, hormones, or cross-sex affirmation counseling, some healthcare providers recommended watchful waiting, talk therapy that affirms a person's biological sex, or psychological or psychiatric treatment of comorbid conditions, as distinct from permanent surgical or hormonal interventions.²²⁶ These providers explained that patients with gender dysphoria can work with a psychiatrist or counselor to better understand their feelings and emotions, and how the incongruence between their psychological identity and biological sex causes them distress. Some clinicians stated that reinforcing a patient's perception that there is something wrong with their body is damaging both to mental and physical health of transgender patients.

Some medical professionals discussed the long-term and irreversible physical effects of cross-sex hormones and puberty blockers, pointing to permanent deepening of voice, clitoromegaly, jaw enlargement, permanent sterility, and sexual dysfunction.²²⁷ Doctors also commented that clinical data have not shown that such hormonal treatments improve the long-term psychological functioning of gender dysphoric

persons. Clinicians stated that certain hormone treatments given to persons with gender dysphoria result in glucose and lipid metabolism disorders and cardiovascular conditions. Some clinicians were critical of the research supporting transition services, stating that it does not adequately assess such long-term health consequences and ignores a particularly vulnerable population of patients, namely the growing population of transitioned individuals who wish to transition back but are being ignored or impeded from receiving services affirming their biology.²²⁸ They cited research indicating that patients did not need surgical or hormonal transition services when less drastic interventions would have been effective.²²⁹ Clinicians stated that transition services were burdensome on these patients on several levels—financially, physically, and psychologically. Commenters concluded that repeal of the 2016 Rule would relieve the burden on these transgender individuals by letting providers decide, based on their assessment of individuals, what surgeries or treatments are appropriate according to their medical judgment and without coercive regulatory pressure.

Some medical providers raised concerns that prescription of sex-reassignment procedures and treatments had risked the health of young patients under their care due to lack of capacity at young ages to fully consent to treatments, difficulties with proper diagnosis during changes undergone in adolescence, and the negative impacts on bone mass and growth, emotional development, and sexual function.²³⁰

²²⁸ Commenters cited, for example, Miroslav L. Djordjevic et al., *Reversal Surgery in Regretful Male-to-Female Transsexuals After Sex Reassignment Surgery*, 13 *J. of Sexual Med.*, 1000, 1006 (2016).

²²⁹ Commenters cited, for example, Joe Shute, "Sex change regret: Gender reversal surgery is on the rise, so why aren't we talking about it?" *The Telegraph* (Oct. 1, 2017), <https://www.telegraph.co.uk/health-fitness/body/gender-reversal-surgery-rise-arent-talking>.

²³⁰ Commenters cited, for example, Lieke Josephina Jeanne Johanna Vrouwenraets, M.Sc., et al., "Early Medical Treatment of Children and Adolescents With Gender Dysphoria: An Empirical

Some clinicians stated that gender dysphoria is not an immutable mental health condition and, as such, the appropriate treatment is not physical and permanent. Some clinicians stated that current care for gender dysphoria includes accommodation counseling, the "wait and see" approach, and (where indicated) detransition therapy, because dysphoria, particularly in children, has a high rates of resolving without other interventions. They said that in their medical judgment, sex reassignment, cross-sex hormones, and affirming counseling are new and controversial treatments with known permanent and negative health consequences. Some medical clinicians criticized the WPATH standards²³¹ for coming to policy conclusions without adequate clinical evidence and recommending treatments that are still experimental.²³² Other commenters criticized the 2016 Rule for relying on the policy recommendations of an international advocacy group to

Ethical Study," *Journal of Adolescent Health* (Jan. 12, 2015), <https://www.ncbi.nlm.nih.gov/pubmed/26119518>; and Guido Giovanardi, "Buying time or arresting development? The dilemma of administering hormone blockers in trans children and adolescents," *Porto Biomedical Journal* (2017).

²³¹ See Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People 16 (7th ed. 2011), <https://www.wpath.org/publications/soc>.

²³² Clinicians stated that the WPATH Standards ignored research evidence in support of a "wait and see" approach that gender dysphoria during childhood has a desistance rate, without drastic surgical or medical intervention for sex-reassignment or affirmation for social transition. They cited studies including Singh, D., "A Follow Up Study of Boys with Gender Identity Disorder," doctoral dissertation submitted at University of Toronto (2012); Drummond, K. D., Bradley, S. J., Badali-Peterson, M., & Zucker, K. J., "A follow-up study of girls with gender identity disorder," *Developmental Psychology* 44:1 (2008), 34–45; Wallien, M. S. C., & Cohen-Kettenis, P. T., "Prediction of adult GID: A follow-up study of gender-dysphoric children," paper presented at the meeting of the World Professional Association of Transgender Health, Chicago, IL (2007); and Smith, Y.L., Van Goozen, S.H., & Cohen-Kettenis, P. T., "Adolescents with gender identity disorder who were accepted or rejected for sex reassignment surgery: A prospective follow-up," *Journal of the American Academy of Child & Adolescent Psychiatry*, 40:4 (2001), 472–81.

²²⁶ Commenters cited sources including Monique Robles, "Observations in a Gender Diversity Clinic," 44 *Ethics & Medics* 2 (Feb. 2019); and Devita Singh, Ph.D., "A Follow-up Study of Boys with Gender Identity Disorder," Department of Human Development and Applied Psychology, Ontario Institute for Studies in Education, University of Toronto (2012).

²²⁷ Commenters cited sources including Talal Alzahrani, M.D., et al., "Cardiovascular Disease Risk Factors and Myocardial Infarction in the Transgender Population," *Circulation: Cardiovascular Quality and Outcomes* 12:4 (Apr. 2019), <https://www.ncbi.nlm.nih.gov/pubmed/30950651>; and Darios Getahun, M.D., et al., "Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons," *Annals of Internal Medicine* (July 10, 2018), <https://www.ncbi.nlm.nih.gov/pubmed/29987313>.

interpret U.S. nondiscrimination laws and develop policy in the American healthcare sector. Other commenters disputed the conclusions of medical professional associations referenced above, stating that they had mischaracterized the medical data, and that life-altering transition interventions are not medically necessary, effective, or safe.²³³

Several commenters who expressed objections to the 2016 Rule clarified that they do not exclude patients from access to healthcare on the basis of the patient's gender identity, but rather objected to the rule requiring that they provide treatment that would be detrimental to the health and well-being of their patients. Part of their medical profession involves recommendations on which treatments will appropriately treat medical conditions to improve the health of their patients, and the choice not to provide transition surgery or abortion is part of those judgments. Some providers indicated that the options for treatment they recommend for patients with gender dysphoria are therapeutic and accommodative counseling to improve long-term health outcomes, particularly of young patients.

Other commenters said the Department should rely on the recent reviews of the clinical data on sex-reassignment surgery and cross-sex hormonal treatment by science and healthcare professionals at HHS and DOD.

Response: These comments further reinforce the Department's conclusion, discussed above in the section on gender identity, that there is no medical consensus to support one or another form of treatment for gender dysphoria. In the Department's current view, the 2016 Rule did not give sufficient evidence to justify, as a matter of policy, its prohibition on blanket exclusions of coverage for sex-reassignment procedures. The Department shares commenters' judgment that the 2016 Rule relied excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding—such as the fact-finding that CMS undertook in deciding to not issue a National Coverage Determination with respect to sex-reassignment surgeries (as discussed above) due to insufficient proof of medical necessity. In addition, commenters identify a lack of clarity in

the 2016 Rule's mandate, because of the lack of medical consensus as to what is even encompassed within "gender transition procedures" (e.g., whether they include facial reconstruction or hair transplants). All these are further reasons why, as a matter of policy, Federal civil rights law should not be used to override providers' medical judgments regarding treatments for gender dysphoria. But as stated above, even if it were appropriate policy, such an end could not be achieved through application of Section 1557 and Title IX. There is no statutory authority to require the provision or coverage of such procedures under Title IX protections from discrimination on the basis of sex.

Comment: Some commenters state that the provisions in § 92.207(b)(3) through (5) of the 2016 Rule were confusing, overbroad, unclear, and inconsistent. Commenters stated that specificity in this area is necessary for efficient and transparent operation of the health insurance coverage to work for all involved. Commenters expressed concerns that the 2016 Rule did not address whether insurers are required to pay for all such surgeries, including without prior approval; approve them absent some standard of medical necessity; or approve them even over concerns of later malpractice lawsuits by the patient. A commenter reiterated his comments on the 2015 NPRM that the 2016 Rule's requirements related to gender transition were confusing for covered entities. The commenter said the regulatory requirement did not address which healthcare providers must provide these surgeries: e.g., plastic surgeons, thoracic surgeons, general surgeons, or physicians whether or not they ordinarily perform major surgery. Others stated that although the 2016 Rule preamble characterized the categorical exclusion provision as a "limited" exception, the provisions on gender transition-related services were very broad and could include facial feminization or masculinization surgeries. Some commenters interpreted "gender dysphoria" as only affecting transgender individuals who seek sex re-assignment services, but other commenters cited clinical data indicating that men who had genital combat injuries and women who had removal of cancerous tissue in breasts and have received the diagnosis may also experience body dysmorphia.²³⁴

Other commenters stated that surgical sex reassignment (which may also include cross-sex hormonal treatment) may cost up to \$22,025 on average for those covered by insurers. Still others said that the definition of "gender dysphoria" itself has changed rapidly and unpredictably over the years, leading to confusion, and point to its shifting conception as an experience of distress or a personal characteristic, to different and changing terms used for diagnosis of gender dysphoria in the DSM, and to the varied use of both clinical medical terms and sociological identity terms concerning the topic. The American Psychiatric Association justified the abandonment of the term "gender identity disorder" and its replacement with "gender dysphoria" in the Diagnostic and Statistical Manual of Mental Disorders to reduce stigmatization of the particular mental condition, but commenters noted that the DSM-5 made no changes to remove the classification of "disorder" for suicidal ideation, other body dysmorphias, or substance use disorder, which mental health advocates commented are also stigmatizing and may be comorbid with gender dysphoria.

Response: The Department agrees that the 2016 Rule made confusing and overbroad demands on covered entities, including insurance providers, and left unclear to what extent it was requiring providers to provide, or health insurance issuers to cover, treatments such as facial feminization, Adam's apple reduction, and hair transplants as part of "health services related to gender transition." This final rule seeks to handle issues involving the exercise of legitimate medical judgment (including determinations relating to medical necessity and coverage decisions) with greater care, and to provide covered entities with greater clarity regarding their regulatory obligations.

Comment: Some commenters who identified as transgender patients opposed the proposed rule on the grounds that they had budgeted and planned with the expectation that there would be a limited or no cost for transition services due to the 2016 Rule, but they were surprised when they had an out-of-pocket cost not covered by their selected insurance company or plan. A much higher cost for these services resulted in the inability to receive or delay in receiving such services. They described surprise billing at multiple steps of the process, from reviewing health insurance coverage plans to waiting for reimbursements. These commenters stated that they anticipated and relied on OCR's 2016

²³³ See Michelle Cretella, "Gender Dysphoria in Children" (November 2018) (American College of Pediatricians policy statement); see also James Cantor, "American Academy of Pediatrics Policy and Trans- Kids: Fact-Checking," *Sexology* (Oct. 2018).

²³⁴ Commenters cited M. Jocelyn Elders, et al., "Medical Aspects of Transgender Military Service," *Armed Forces and Society* 41(2) (Mar. 2014): 199–220.

Rule as guaranteeing them insurance coverage because it is provided to other patients, and that this was their understanding of the Affordable Care Act and their civil rights protections. Other commenters contended that the 2016 Rule had caused the reduction of blanket exclusions for gender transition in health insurance coverage over the past three years.²³⁵ Others stated that short-term limited duration insurance plans do not provide coverage of gender transition-related services, and therefore if transgender individuals are covered by such plans, they would not be able afford medically necessary services.

Response: With respect to coverage for gender transition services, the Department notes that this final rule makes no changes to what has been the status quo since December 2016, when the Department was enjoined from enforcement of the gender identity provisions of the 2016 Rule; such provisions have now been vacated by a court. Any recent decrease in blanket exclusions for sex-reassignment coverage is therefore more likely to be attributable to health insurance issuer or plan sponsor choice. State-level legal requirements concerning gender identity coverage have also come into effect in recent years, such as State statutes, regulations, guidance,²³⁶ and court orders²³⁷—this final rule does not affect those changes in any way. But to the extent that provisions in the 2016 Rule did pressure any insurers to cover services on the basis of gender identity that they previously had not covered, such provisions did so without statutory authority, which is why they were preliminarily enjoined and vacated.

As a policy matter, the Department recognizes that surprise billing is a serious problem, but that topic is not a subject of this rulemaking. As for short-

term limited duration insurance, for reasons discussed below, it is generally not regulated under this final rule and so is generally not affected by the rule's nondiscrimination requirements in any case.

e. Discrimination on the Basis of Association, Repeal of § 92.209 of the 2016 Rule

The Department proposed to repeal § 92.209 of the 2016 Rule, which included a prohibition on discrimination against an individual or entity on the basis of being known to or believed to have a relationship or association.

Comment: Commenters opposed the repeal of prohibitions against discrimination based on association with a protected category. These commenters contended that removing such protections would cause confusion, both for covered entities who will be unsure of their responsibilities and for individuals who will be unsure of their rights, especially in light of other Federal nondiscrimination laws that the Department enforces. For example, the Department enforces Title II of the ADA and its implementing regulation, which prohibits discrimination against an individual based on his or her association with another individual with a disability, as do Titles I and III of the ADA.²³⁸ Commenters said that this also shows that it would defy Congressional intent, and cause inconsistency among different regulations that covered entities are subject to, if the Department were to withdraw associational discrimination protections from patients seeking healthcare. Commenters also expressed concern that the proposed rule would make it more difficult for those experiencing discrimination by association to enforce their rights. Other commenters stated that the lack of reference to associational discrimination in the proposed rule is inconsistent with existing case law that validates prohibitions on associational discrimination, particularly in employment discrimination cases brought under Title VII pertaining to race, sex, and religion. Others argued that it is incorrect to assume that by referencing the grounds protected under previous civil rights laws, Section 1557 automatically incorporates the limitations found in those laws.

Some commenters contended that specific protected populations are more susceptible to associational

discrimination. In particular, commenters stated that deaf and hard-of-hearing patients frequently use hearing companions, especially in hospital settings, and may be subject to associational discrimination.

Commenters also identified potential instances of associational discrimination, including an entity's refusing to provide medical services to a white individual due to association with an African American individual, refusing to provide medical services to a child because his parents speak a different language, or refusing to provide services to an individual because her family members have a specific disability.

Response: This final rule neither abrogates nor withdraws any protections available under the incorporated civil rights statutes or their implementing regulations. It simply declines to use the Section 1557 regulation to identify protections beyond those specifically identified in the text of the relevant statutes and regulations. Protections against discrimination on the basis of association will be available under this final rule to the extent that they are available under those statutes and regulations. As stated above, the Department regards this as the best way to decrease confusion. As the *Franciscan Alliance* court noted, the executive branch is obligated to implement Section 1557, with the civil rights statutes it incorporates, by "giving the statutory text its plain and ordinary meaning, construing the statute as a whole, and giving effect to every word of the statute."²³⁹ Courts have held that Section 1557 incorporates the limitations of the civil rights statutes referenced in Section 1557.²⁴⁰

Some instances discussed by commenters would appear to constitute discrimination against a person under the underlying civil rights statutes even without the 2016 Rule's prohibition on associational discrimination. For example, if a covered entity refused to provide meaningful access for LEP parents who are legally entitled to make medical decisions on behalf of their child, it could constitute discrimination on the basis of national origin.

f. Multiple Protected Statuses

The Department received many comments about individuals who may have protected status or face discrimination on multiple grounds.

²³⁹ *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660, 690 (N.D. Tex. 2016).

²⁴⁰ See, e.g., *Condry v. UnitedHealth Group*, 2018 WL 3203046 (N.D. Cal. Jun 27, 2018) ("disparate impact claims on the basis of sex are not cognizable under section 1557").

²³⁵ Commenters cited sources including, e.g., Out2Enroll, Summary of Findings: 2019 Marketplace Plan Compliance with Section 1557 (finding that 18.5% of insurers in 2017, 28% of insurers in 2018, and 94% of the insurers did not include blanket exclusions in their plans).

²³⁶ See, e.g., Calif. Health and Safety Code 1365.5; Colo. Insurance Bulletin No. B-3.49; Conn. Insurance Bulletin IC-34; 79 Del. Laws Ch. 47; DC Code 31-2231.11; Haw. Rev. Stat. 431:10A-118.3, 432:1-607.3, 432D-26.3; 50 Ill. Adm. Code 2603.35; Mass. Insurance Bulletin 2014-03; Nev. Rev. Stat. 651.070; Nev. Admin. Code 686A.140(7); 11 New York Codes Rules and Regulations 52.16; New York Insurance Code 2607, 3243, 4330; Ore. Rev. Stat. 746.015; Ore. Admin. Rules 836-080-0055; 46 Pa. Bulletin 2251; Rhode Island Health Insurance Bulletin 2015-3; 8 Va. Stat. Ann. 4724; Vt. Insurance Bulletin 174; Wash. Rev. Code 48.30.300.

²³⁷ See, e.g., *Outfront v. Piper*, No. 62-cv-15-7501 (Minn. D. Ct. Nov. 14, 2016) (interpreting the state Constitution as applied to MinnesotaCare); *Good v. Iowa Dept. of Human Services*, No. 18-1158 (Iowa S. Ct. Mar. 8, 2019) (interpreting the Iowa Civil Rights Act as applied medical assistance).

²³⁸ 28 CFR 35.130(g) (Title II); 42 U.S.C. 12112(b)(4) (Title I); 42 U.S.C. 12182(b)(1)(E) (Title III).

Comment: One commenter stated that because the 2016 Rule covers discrimination based on multiple protected statuses, the proposed rule would create a confusing mix of legal standards and available remedies and therefore could limit claims of intentional discrimination, while the 2016 Rule makes it easier for members of the public to file complaints of intersectional discrimination in one place.

Response: OCR has long accepted complaints alleging discrimination based on more than one protected status. OCR has handled those complaints, and will continue to handle them, under the implementing regulations of each of its applicable civil rights laws. Nothing in this final rule changes that. OCR's complaint form provides the public with the option to select multiple forms of prohibited discriminatory practices, such as both race and disability. OCR continues to encourage the public to file complaints about potentially unlawful discrimination, whether on one prohibited basis or on multiple prohibited bases.

Comment: Commenters stated that the proposed rule would compound discrimination faced by individuals with multiple protected characteristics, such as people of color who are also LEP or disabled. Some commenters said that African Americans are more likely to live with disabilities and chronic conditions, and thus would be disproportionately affected by relaxing discrimination restrictions for health insurance plans.

Response: The Department commits itself, in this final rule, to fully enforce Section 1557 according to its text and the text of the underlying statutes, as well as under the Department's implementing regulations for those statutes, as applied to the health context. Although the Department is proposing to repeal the nondiscrimination provision of the 2016 Rule at § 92.101, this final rule replaces it with a general provisions section at § 92.2. The new section will maintain the nondiscrimination requirements required by Title VI, Title IX, the Age Act, and Section 504. As such, individuals with multiple protected characteristics, such as race and disability, would be protected under the Department's enforcement of Section 1557 to the extent those statutes and regulations apply. Those statutes and regulations explain which characteristics are protected.

With respect to LEP and disability, this final rule additionally contains specific sections clarifying those

protections. The underlying regulations and guidance for enforcing these statutes establish standards that are well-known by covered entities. The Department will continue to robustly enforce these statutes, and believes this final rule provides appropriate language to ensure that enforcement occurs.

Comment: Commenters contend that African American, Asian American and Pacific Islander, and Native American women are more likely to die from pregnancy-related complications and will be disproportionately affected by changes to the interpretation of sex discrimination in the proposed rule. Others contend that LGBT people of color will be harmed by the proposed regulation; they also state that LGBT people of specific national origins, including Native American and Middle Eastern, experience high rates of negative experiences in healthcare settings related to gender identity. Commenters alleged the proposed rule would disproportionately harm Native American women, women of color, and transgender individuals who are minorities.

Response: As discussed above, the 2016 Rule's definition of "on the basis of sex" is not included in this final rule because it exceeded the Department's statutory authority. In addition, with respect to gender identity and termination of pregnancy, the court's longstanding preliminary injunction and eventual *vacatur* of that language means that the results some commenters fear from removing such language would not be the result of this final rule. The Department is not aware of data supporting commenters' assertion that this change will have a disparate impact on the basis of race or national origin, although even if it did, that disparate impact would be attributable to the statutes rather than to this final rule. To the extent that the Department learns that individuals suffer barriers to healthcare on the basis of race, national origin, or any other protected characteristic, it will work to address those barriers within the limits of its statutory authority.

g. Examples of Discriminatory Practices (Repeal of § 92.207 of the 2016 Rule)

The Department proposed to repeal § 92.207 of the 2016 Rule, which stipulated that covered entities must not discriminate on the prohibited bases in providing or administering health-related insurance or other health-related coverage, and listed examples of such prohibited discrimination. Comments pertaining to § 92.207(b)(3)–(5) related to gender identity are discussed above

in the section on discrimination on the basis of sex.

Comment: Commenters opposed repealing the explicit provisions of § 92.207 that prohibit covered entities from discriminating in health insurance or other health coverage. Commenters argued that the proposed rule did not provide any reasoned legal or policy basis for the repeal, which precluded the opportunity to provide public comment on the Department's justifications and so violated the APA. While the proposed rule discussed repealing provisions that may be duplicative, inconsistent, or confusing, commenters argued that the Department did not explain under which of these grounds it was repealing § 92.207, and that the proposed rule's supporting footnote²⁴¹ listed comparator regulatory citations that did not duplicate or contradict the provisions of § 92.207.

Commenters also expressed concern that repealing this section would allow health insurance issuers to discriminate, particularly with regard to benefit design, and could make it harder for people who experience discrimination to enforce their rights through administrative and judicial complaints. Commenters asserted that, prior to the ACA, health insurance issuers avoided covering costly individuals by employing the discriminatory practices prohibited by § 92.207, and that repealing these explicit prohibitions would allow health insurance issuers to again discriminate in a variety of ways, including by excluding or denying benefits, applying age limits, increasing costs for sicker enrollees, imposing utilization management limitations, and designing discriminatory prescription drug formularies. Commenters also argued that the ACA was intended to increase administrative oversight of private health insurance plans and to prevent discrimination in health insurance, particularly in light of the underlying civil rights laws' historically limited application to private health insurance and benefit design prior to the ACA.

Several commenters argued that the removal of specific nondiscrimination provisions under § 92.207 would make the regulation vague, eliminate guidance for covered entities, and create confusion about what is prohibited conduct, thereby increasing legal

²⁴¹ 84 FR at 27869 n.147 (comparing 45 CFR 92.207 with "45 CFR 80.5 (health benefits under Title VI), 84.43 (health insurance under Section 504), 84.52 (health benefits under Section 504), 84.33 (rule of construction of Section 504 vis-à-vis validly obligated payments from health insurer); 86.39 (health insurance benefits and services under Title IX).").

uncertainty and risk. This argument was reiterated by some State government regulators, who said that the specificity in the law provides clarity for both covered entities and the State, with State regulators often relying upon the standards in the 2016 Rule to ensure nondiscrimination in health insurance. Other commenters said that the repeal of § 92.207, compounded with the repeal of language access and taglines requirements, would open the door to discrimination based on national origin by healthcare providers.

Response: The number, breadth, and depth of comments received and discussed in this preamble indicate that the public was given an adequate opportunity to provide comment on the Department's justifications for this final rule.

Commenters are correct to note that the ACA has significantly expanded the applicability of Federal civil rights laws to private health insurance plans. That is why, under this final rule, all health insurance programs that remain covered by Section 1557 remain prohibited from discriminating on the grounds specified by the statute. This final rule has a section on scope at § 92.3, and the Department does not believe the rule needs an additional or separate section on health insurance in order to make this clear. OCR will examine carefully any allegations of discrimination by health insurance issuers, including through benefit design, and will vigorously enforce Section 1557's prohibitions. The Department also notes that certain health insurance issuers remain subject to similar nondiscrimination requirements under statutory provisions implemented and the regulations issued by CMS's Center for Consumer Information and Insurance Oversight (CCIIO). Commenters' specific concerns about national origin discrimination are addressed above and below in the relevant sections.

The 2019 NPRM listed § 92.207 among passages of the 2016 Rule that "are duplicative of, inconsistent with, or may be confusing in relation to the Department's preexisting Title VI, Section 504, Title IX, and the Age Act regulations."²⁴² As the footnote referenced by commenters shows, the Department specifically pointed there to preexisting HHS regulations under those statutes regarding health benefits and health insurance.²⁴³ The substantive overlap between these regulations and § 92.207 is sufficient to show that the latter either duplicates them, or is

inconsistent with them, or may be confusing as to whether it is duplicating them or contradicting them. Because Section 1557 does not require a regulation, the Department prefers to enforce the relevant statutes, to the extent possible, through their existing regulations. The changes in the 1557 regulation made by this final rule advance the Administration's goal of reducing the regulatory burden of the ACA and of administrative action in general.²⁴⁴

The 2016 Rule's list of examples of prohibited conduct by insurers at § 92.207(b) was followed by a catchall provision at § 92.207(c) stipulating that the enumeration of those specific forms of discrimination was no limitation on the general prohibition on insurers' discriminating on the prohibited grounds. That catchall provision made § 92.207 no less vague, and gave it no less potential to cause confusion, than this final rule's general prohibition on discrimination by covered entities. The Department declines in this preamble to give guidance of this kind to State regulators, who must each work within their own State's regulatory framework for health insurance. The Department notes that State regulators may also rely upon regulations issued by CCIIO, as applicable.

h. Summary of Regulatory Changes

For the reasons discussed herein, and considering the comments received, the Department finalizes its proposed new § 92.2 without change, its repeal of § 92.4 without change, its repeal of the notice requirement in § 92.8(d) and Appendix B without change, and its repeal of § 92.101, 92.206–92.207, and 92.209 without change.

(5) Assurances in Proposed § 92.4, and Repeal of § 92.5 of the 2016 Rule

The Department proposed that the 2016 Rule's provision at § 92.3 requiring an assurance of compliance with Section 1557 be retained and redesignated § 92.4. 84 FR at 27863. Here, as throughout the proposed rule, the Department also updated the 2016 Rule's term "State-based MarketplaceSM" to read "State Exchange," in conformity with current CMS regulations. 84 FR at 27871.

Comment: Comments contended it is unclear whether submitting assurances

required under this provision at § 92.4 would also fulfill the assurance requirements of Section 504 at 45 CFR 84.5.

Response: As under the 2016 Rule, the application package for all HHS grant-making agencies continues to include a requirement that the applying entity submit a signed assurance form (Form 690), which specifically references Section 1557 along with Title VI, Title IX, Section 504, and the Age Act. That form is available at <https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf>. All recipients of Federal financial assistance from HHS are required to submit the consolidated form that satisfies the assurance requirements for both Section 1557 and these four other civil rights statutes.

The Department requested comment on whether this proposal struck the proper balance by retaining the assurance provisions from the 2016 Rule, and whether the benefits of these provisions exceed the burdens imposed by them.

Comment: Some commenters expressed their support for maintaining the current assurance of compliance requirement, noting that an assurance of compliance is an important step towards ensuring that covered entities know their obligations under Section 1557 and remain compliant. Additionally, questions were raised regarding which entity would be responsible for oversight, enforcement, and corrective action should a covered entity violate Section 1557 despite assuring its compliance.

Response: OCR is responsible for enforcing Section 1557 and will provide oversight, enforcement, and corrective action should a covered entity violate its obligations under Section 1557. The Department agrees that assurances of compliance provide valuable services by alerting covered entities of their obligations, and will retain these provisions under § 92.4 of this final rule.

Summary of Regulatory Changes: For the reasons given in the proposed rule, and having considered comments received, the Department finalizes its proposed § 92.4, and repeal of § 92.5 of the 2016 Rule, without change.

(6) Enforcement Mechanisms in Proposed § 92.5, and Repeal of §§ 92.6, 92.7, 92.8, 92.101, 92.301, 92.302, 92.303, and Appendices A and C of the 2016 Rule

The Department proposed provisions on enforcement of Section 1557 at the new § 92.5, 84 FR at 27863, and proposed to repeal §§ 92.6, 92.7, 92.8, 92.101, 92.301, 92.302, 92.303, and

²⁴² 84 FR 27869.

²⁴³ See 84 FR at 27869 n.147.

²⁴⁴ Executive Order 13765 on Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal, 82 FR 8351 (Jan. 20, 2017); Executive Order 13771 on Reducing Regulation and Controlling Costs (Jan. 30, 2017); Executive Order 13777 on Enforcing the Regulatory Reform Agenda (Feb. 24, 2017); Executive Order 12866 on Regulatory Planning and Review, 58 FR 190 (Oct. 4, 1993), at § 1(b)(10).

Appendices A and C of the 2016 Rule, which also provided for enforcement mechanisms and notices.

a. Enforcement Procedures and Underlying Regulations in § 92.5(a) (Repeal of § 92.302 and § 92.6(a) of the 2016 Rule)

Proposed § 92.5(a) applies the enforcement mechanisms provided for, and available under, Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or Section 504 of the Rehabilitation Act of 1973, with their respective implementing regulations, to Section 1557.

Comment: Various commenters expressed opposition to the Department's proposal to replace § 92.301 with § 92.5, and requested that the Department retain § 92.301. Others expressed the view that by adopting § 92.5, the Department would be incorrectly limiting the remedies available under Section 1557. Several commenters asserted that enforcement would be more difficult under the proposed rule because, they said, it creates a patchwork of legal standards—unlike the 2016 Rule, which used a single standard that permitted disparate impact claims. They said this would create confusion, hamper enforcement, and dilute the protections provided to individuals.

Response: This final rule properly limits the remedies available under Section 1557. The text of the 2016 Rule, at § 92.301(a), stated that the enforcement mechanisms available and provided for under Title VI, Title IX, Section 504 and the Age Act shall apply for the purposes of Section 1557.²⁴⁵ But upon reconsideration of these issues, the Department concludes the 2016 Rule applied these mechanisms in a confusing and inconsistent manner. For certain covered entities, it applied Title VI mechanisms, not only to grounds of discrimination prohibited under Title VI, but also to those prohibited under Title IX and Section 504, while leaving Age Act mechanisms in place for the grounds of discrimination it prohibits; for other covered entities, it applied Section 504 mechanisms, not only to grounds of discrimination prohibited under Section 504, but also to those prohibited under Title VI, Title IX, and the Age Act.²⁴⁶ The 2016 Rule's regulatory structure blended new standards and preexisting standards from underlying civil rights regulations, and imposed those standards alongside

the underlying regulations, which were left in place. In contrast, this final rule adopts the enforcement mechanisms for these four statutes and their implementing regulations *respectively*, each for its own statute. The Department believes this minimizes the patchwork effect of the 2016 Rule by using a familiar regulatory regime under those four statutes. The Department also believes this approach is what the statutory text contemplates. Moreover, because OCR has significant experience enforcing civil rights claims using these civil rights statutes' regulations, the Department expects this change to improve enforcement of Section 1557 and, by removing possible confusion, to make it easier for both individuals and covered entities to know their rights and responsibilities.

Comment: One commenter said that the Department's proposal to remove the 2016 Rule's single standard for enforcing claims is inconsistent with the Minnesota District Court's finding in *Rumble v. Fairview Health Services* that "Congress intended to create a new, health-specific, anti-discrimination cause of action that is subject to a singular standard, regardless of a plaintiff's protected class status."²⁴⁷

Response: The Department disagrees with this commenter's suggestion that it is inappropriate to finalize the proposed rule's repeal of provisions containing certain enforcement mechanisms. The Minnesota District Court found the language of the Section 1557 statute to be "ambiguous, insofar as each of the four statutes utilize[s] different standards for determining liability, causation, and a plaintiff's burden of proof,"²⁴⁸ and concluded that the Department's interpretation of Section 1557 was permissible. However, the Minnesota District Court view is the minority view and has subsequently been rejected by multiple other court rulings that postdate the 2016 Rule.²⁴⁹

²⁴⁷ 2015 WL 1197415, at *11 (D. Minn. Mar. 16, 2015).

²⁴⁸ *Id.* at *10.

²⁴⁹ See *Briscoe v. Health Care Svc. Corp.*, 281 F. Supp. 3d 725, 738 (N.D. Ill. 2017) ("Taken together, the first two sentences of § 1557 unambiguously demonstrate Congress's intent 'to import the various different standards and burdens of proof into a Section 1557 claim, depending upon the protected class at issue.'"), quoting *Southeastern Pennsylvania Transp. Auth. v. Gilead Sciences Inc.*, 698–99 (E.D. Pa. 2015); *York v. Wellmark, Inc.*, 2017 WL 11261026, at *18 (S.D. Iowa Sept. 6, 2017) ("Congress clearly intended to incorporate the statutes' specific enforcement mechanisms rather than create a general catch-all standard applicable to all discrimination claims."). See also *Galuten on Behalf of Estate of Galuten v. Williamson Med. Ctr.*, 2019 WL 1546940, at *5 (M.D. Tenn. Apr. 9, 2019) (same); *E.S. by and through R.S. v. Regence BlueShield*, 2018 WL 4566053, at *4 (W.D. Wash. Sept. 24, 2018); *Doe v. BlueCross BlueShield of*

The Department agrees with these latter courts' reasoning. To the extent that the statutory language could be ambiguous, as the Minnesota district court concluded, the Department believes that its new interpretation is a better and reasonable interpretation of the statute, and is at least an equally permissible statutory interpretation, and therefore is entitled to *Chevron* deference, *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). That the Department's interpretation represents a break with a previous interpretation does not preclude the Department from reinterpreting the statute and receiving *Chevron* deference for its new interpretation, see, e.g., *Rust v. Sullivan*, 500 U.S. 173, 186–87 (1991). Here, the Department believes that this final rule's approach is the one best suited to reducing confusion and robustly enforcing Section 1557's nondiscrimination provisions.

b. Compensatory Damages (Repeal of § 92.301(b) of the 2016 Rule)

The Department proposed to repeal § 92.301(b) of the 2016 Rule, which provided for compensatory damages for any and all claims under Section 1557.

Comment: Some commenters opposed the changes to the enforcement mechanisms under the proposed rule and asserted that Section 1557 makes available to all individuals any of the enforcement mechanisms available under any of the four civil rights statutes, including but not limited to compensatory damages.

Response: Although the 2016 Rule stated that compensatory damages are available in appropriate administrative and judicial actions under the Section 1557 regulation, the Department has concluded that its enforcement of Section 1557 should conform to the Department of Justice's Title VI Manual. 84 FR at 27851. The manual states that, under applicable Federal case law, compensatory damages are generally unavailable for claims based solely on a Federal agency's disparate impact regulations.²⁵⁰ Consequently, the Department considers it most appropriate to finalize this rule by eliminating § 92.301(b) and reverting to enforcement under the regulations applicable to Title VI, Title IX, the Age Act, or Section 504. To the extent compensatory damages are, or are not,

Tennessee, Inc., 2018 WL 3625012, at *6 (W.D. Tenn. July 30, 2018).

²⁵⁰ See DOJ Title VI Manual, <https://www.justice.gov/crt/fcs/T6Manual9> (citing *Alexander v. Sandoval*, 532 U.S. 275, 282–83 (2001), *Barnes v. Gorman*, 536 U.S. 181, 187 (2002), and *Geber v. Lago Vista Indep. Sch.*, 524 U.S. 274, 87 (1998)).

²⁴⁵ 81 FR 31472.

²⁴⁶ *Id.*

available under those regulations, the regulations will provide for enforcement of Section 1557 in applicable circumstances in the same way.

This approach is consistent with both the best interpretation of the text and the court decisions (cited above) indicating that Section 1557 does not impose a single standard but instead incorporates the distinct enforcement mechanisms of each of the four civil rights statutes described in Section 1557.²⁵¹

c. Implied Private Rights of Action (Repeal of § 92.302(d) of the 2016 Rule)

The Department proposed to repeal § 92.302(d) of the 2016 Rule, which stated that an individual or entity may bring a civil action in a United States District Court to challenge a violation of Section 1557 or the 2016 Rule.

Comment: Some commenters opposed repeal of this language. Several commenters argued that the existence of a private right of action is clear from the statutory language in Section 1557, which they say explicitly references and incorporates the enforcement mechanisms of the four civil rights laws listed, including a private right of action. They cited cases that allow for Section 1557 to include enforcement mechanisms separate from the mechanisms in underlying statutes.²⁵² Commenters said that the creation of a private right of action within Section 1557 is consistent with Congress's intent that civil rights laws be broadly interpreted to effectuate the remedial purposes of those laws, and that removing Section 1557's private right of action is inconsistent with precedent of the United States Supreme Court, which

has upheld private rights of action under the preexisting civil rights laws.

Response: Upon reconsideration of this issue, the Department no longer intends to take a position in its regulations on the issue of whether Section 1557 provides a private right of action. To the extent that Section 1557 permits private rights of action, plaintiffs can assert claims under Section 1557 itself rather than under the Department's Section 1557 regulation.

Comment: Commenters requested that the Department adopt a regulatory framework for Section 1557 where there is a requirement for exhaustion of administrative remedies before a party can bring a private right of action.

Response: Because the Department is eliminating the language specifying a right to sue, the Department does not consider it necessary to establish a framework and a requirement for exhaustion of administrative remedies before filing suit in court.

d. Voluntary Action (Repeal of § 92.302(c) and § 92.6(b) of the 2016 Rule)

The Department proposed to repeal § 92.302(c) of the 2016 Rule, as well as § 92.6(b), which set forth provisions concerning voluntary cooperation with requests for information, and voluntary action beyond the requirements of Section 1557. These provisions have parallels in the regulations implementing Title VI, Section 504, Title IX, and the Age Act,²⁵³ which the Department will use to enforce Section 1557.

The Department did not receive comments specific to these sections.

e. Access to Records of Compliance (Repeal of § 92.303(c) of the 2016 Rule)

The Department proposed to repeal § 92.303(c) of the 2016 Rule, which set forth the Department's obligations to permit access by OCR to review records and sources of information, and to otherwise comply with OCR investigations under the 2016 Rule.

Comment: Commenters expressed concern that the proposed rule undermines the Department's enforcement authority concerning compliance with Section 1557 by programs and activities administered by the Department.

Response: The regulations implementing Section 1557's four underlying statutes already contain provisions addressing access to review of covered entities' records of

compliance.²⁵⁴ The language in the 2016 Rule to this effect was unnecessary, as OCR has the tools to review records and sources of information under existing regulations.

f. Prohibitions on Intimidation and Retaliation (Repeal of § 92.303(d) of the 2016 Rule)

The Department proposed to repeal § 92.303(d) of the 2016 Rule, which concerns intimidation and retaliation provisions that pertain to the Department.

Comment: Several commenters contended that under the proposed rule, those bringing Section 1557 claims would no longer be explicitly protected from retaliation and discrimination.

Response: The regulations implementing Section 1557's four underlying statutes already contain provisions against intimidation and retaliation as appropriate.²⁵⁵ The language in the 2016 Rule to this effect was unnecessary. Moreover, OCR ensures the confidentiality of complainants under all the statutes it enforces, to the extent permitted by law and consistent with OCR's investigative needs. In some cases, the Freedom of Information Act, the APA, or other laws may require disclosure of certain information provided by complainants.

g. Perpetuating Discrimination by Assistance and Utilizing Criteria or Methods of Administration (Repeal of § 92.101(b)(1)(ii), (b)(3)(ii), and (b)(4)(ii) of the 2016 Rule)

The Department proposed to repeal § 92.101(b)(1)(ii) and § 92.101(b)(4)(ii), which prohibited significant assistance to any agency, organization, or person that discriminates on the basis of race, color, national origin, or age. The Department also proposed to repeal § 92.101(b)(3)(ii), which prohibited utilization of criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex.

Comment: One commenter objected to repealing the prohibition on the utilization of criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex. Arguing that Section 1557 is its own authority, the commenter stated that it is irrelevant that the Title IX regulations do not

²⁵¹ See *Galuten*, 2019 WL 1546940, at *5 n.8 (because "the Age Discrimination Act would not authorize [] compensatory damages," "it appears that a Federal court with jurisdiction would be constrained to dismiss Plaintiff's claims for compensatory . . . damages under the ACA").

²⁵² Commenters cited *Edmo v. Idaho Dep't of Corr.*, No. 1:17-cv-00151-BLW, 2018 WL 2745898, at *9 (D. Idaho June 7, 2018) ("[C]ross-referencing the statutes and the express incorporation of the enforcement mechanisms from those statutes is probative of Congressional intent to provide both a private right and a private remedy for violations of Section 1557."); *Esparza v. Univ. Med. Ctr. Mgmt. Corp.*, No. 17-4803, 2017 WL 4791185, at *5 (E.D. La. Oct. 24, 2017) (concluding it was "abundantly clear to the Court that Congress intended to create a private right of action to enforce § 1557"); *Doe One v. CVS Pharmacy, Inc.*, 348 F. Supp. 3d 967, 982 (N.D. Cal. 2018) (finding plaintiffs had not sufficiently alleged disparate impact); see also *Cannon v. Univ. of Chi.*, 441 U.S. 677, 703 (1979) (recognizing that Congress intended to create Title IX remedies comparable to those available under Title VI, including a private cause of action for victims of the prohibited discrimination, and finding that age and advanced degrees criteria had a disparate impact on women); *Rumble v. Fairview Health Servs.*, 2015 WL 1197415.

²⁵³ See 45 CFR 80.7(d), § 80.8(c)(1) (Title VI); § 84.6(b) (Section 504); proposed § 86.71 (Title IX incorporating 45 CFR 80.7(d)); § 90.49(c) (Age).

²⁵⁴ See 45 CFR 90.45, § 91.31 (Age Act) and § 80.6(c) (Title VI); 45 CFR 84.61 (Section 504 incorporating 45 CFR 80.6(c)); § 86.71, as finalized here (Title IX incorporating 45 CFR 80.6(c)).

²⁵⁵ See 45 CFR 80.7(e) (Title VI); § 91.45 (Age Act); 45 CFR 84.61 (Section 504 incorporating 45 CFR 80.7(e)); § 86.71, as finalized here (Title IX incorporating 45 CFR 80.7(e)).

contain a disparate impact provision. Some commenters also contended that removing the “significant assistance” provision would undermine enforcement.

Response: The prohibition on perpetuating discrimination by providing significant assistance to any agency, organization, or person that discriminates is identified only in the Title IX and Section 504 regulations, as applied to sex and disability discrimination claims;²⁵⁶ the 2016 Rule applied it also to claims on the basis of race, color, national origin, or age. Similarly, as discussed above in the section on discrimination on the basis of sex, there is no disparate impact language in the Department’s Title IX regulations, but the 2016 Rule made such language applicable to sex discrimination claims brought under Section 1557. For the reasons given earlier in this section, the Department considers it appropriate to rely on the enforcement mechanisms appropriate to each underlying civil rights statute, rather than to create a new and confusing civil rights regulatory framework specific to the enforcement of Section 1557.

h. Notices of Nondiscrimination Rights and Statement of Nondiscrimination Under the 2016 Rule (Repeal of § 92.8 of the 2016 Rule)

The Department proposed to repeal § 92.8 of the 2016 Rule, which required a notice informing individuals about nondiscrimination and accessibility requirements, such as the sample notice and nondiscrimination statement at Appendix A to Part 92.

Comment: Some commenters contended that HHS did not consider how the removal of the 2016 Rule’s notice provisions may result in decreased access to, and utilization of, healthcare by people with disabilities, people with LEP, older adults, people who are LGBT, and other vulnerable populations. These commenters argued that with the notice provision’s removal, these protected populations will be limited in knowing their rights under Federal civil rights laws, and in knowing how to file complaints with OCR if faced with discrimination in a healthcare setting. Others stated that the Department did not provide an evidentiary basis for what it deemed would be a “negligible” impact on people with LEP or “additional societal costs” as a result of removing the notice provisions. Commenters proposed that instead of eliminating the notice

provision, the Department should consider requiring covered entities to provide notice on an annual basis, when updated, and upon request, in order to harmonize with the Health Insurance Portability and Accountability Act (HIPAA)’s annual notice requirements. Other commenters similarly proposed that the Department should consider specifying a number of times that a covered entity should send notice to individuals over the course of a year.

Response: The regulations implementing Section 1557’s four underlying statutes already contain notice provisions.²⁵⁷ The language in the 2016 Rule to this effect was unnecessary.

Individuals belonging to any protected category under Section 1557, including those with disabilities or LEP, remain covered under existing standards regarding notice. The Department is unaware of data suggesting that those regulations have been or are inadequate to their purpose of making individuals aware of their civil rights. To the extent that it discovered such data, it would consider revising each regulation as appropriate.

Each of the relevant underlying regulations has its own unique standards on providing notice, tailored to the purposes of each civil rights statute.²⁵⁸ Compressing these into a single standard under the 2016 Rule has led to an unjustifiable burden and understandable confusion. The Department’s estimates of regulatory burden are discussed in the RIA.

Comment: Some commenters stated the Department should clarify when the notice and taglines requirements will no longer be effective with respect to timeframes such as open enrollment for Exchanges, employer-sponsored plans, and Medicare. Most of these communications are subject to the current notice and taglines requirements under the 2016 Rule. Commenters

sought clarification from the Department as to whether OCR will enforce the notice and taglines requirement against any covered entity from the date of the proposed rule (June 14, 2019).

Response: The changes made in this final rule will be effective 60 days from the publication of this final rule in the **Federal Register**. The 2016 Rule is in effect until that time, except as enjoined or vacated by courts.

Comment: Several commenters requested that the Department retain parts of § 92.8 of the 2016 Rule that require the designation of a responsible employee and grievance procedures, and the text of sample grievance procedures in Appendix C to Part 92. They said that retaining these provisions would increase access to healthcare and retain uniform responsible employee and grievance procedures.

Response: The Department believes it is appropriate to rely on the regulatory framework that has already been set forth for Section 1557’s four underlying statutes. To the extent that those implementing regulations have responsible employee and grievance procedures, they are sufficient for enforcement of Section 1557.

i. Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, the Department finalizes § 92.5, and the proposed repeal of §§ 92.6, 92.7, 92.8, 92.101, 92.301, 92.302, 92.303, and Appendices A and C of the 2016 Rule, without change.

(7) Relationship to Other Laws in Proposed § 92.6, and Repeal of § 92.2(b) and 92.3 of the 2016 Rule

The Department proposed to repeal §§ 92.2(b) and 92.3 of the 2016 Rule, which addressed the application and relationship of Section 1557 and the 2016 Rule to other laws. The Department proposed instead a new § 92.6. The new § 92.6(a) states that nothing in the 1557 regulations shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards applicable under Title VI, Title VII, Title IX, the Age Act, or Section 504, or to supersede State laws that provide additional protections against discrimination on any basis described in § 92.2. The new § 92.6(b) states that insofar as the application of any requirement under the Section 1557 regulations would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections provided by any of the statutes cited in paragraph (a) of this section or provided

²⁵⁶ See 45 CFR 84.4(b)(1)(v) (Section 504); § 86.31(b)(6), as finalized here (Title IX).

²⁵⁷ See 45 CFR 80.6 and Appendix to Part 80 (Title VI), § 84.8 (Section 504), § 86.9 (Title IX) and § 91.32 (Age Act).

²⁵⁸ Title VI, 45 CFR 80.6(d), and the Age Act, 45 CFR 91.32, contain general requirements to provide notice. Section 504 requires more: A covered entity must “take appropriate initial and continuing steps to notify [individuals] that it does not discriminate on the basis of [disability]” and include this information in its “recruitment materials and publications.” 45 CFR 84.8. Title IX goes even further: A covered entity must “prominently” display its notice of nondiscrimination in “each announcement, bulletin, catalog, or application form which it makes available to any [covered person], or which is otherwise used in connection with the recruitment of students or employees” and not “distribute a publication . . . which suggests, by text or illustration, that such [covered entity] treats applicants, students, or employees differently on the basis of sex except as such treatment is permitted by [Title IX].” 45 CFR 86.9.

by the Architectural Barriers Act of 1968 (42 U.S.C. 4151 *et seq.*); the Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008 (42 U.S.C. 12181 *et seq.*); Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d); the Coats-Snowe Amendment (42 U.S.C. 238n); the Church Amendments (42 U.S.C. 300a–7); the Religious Freedom Restoration Act (42 U.S.C. 2000bb *et seq.*); Section 1553 of the Patient Protection and Affordable Care Act (42 U.S.C. 18113); Section 1303 of the Patient Protection and Affordable Care Act (42 U.S.C. 18023); the Weldon Amendment (Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B sec. 209 and sec. 506(d) (Sept. 28, 2018)); or any related, successor, or similar Federal laws or regulations, such application shall not be imposed or required.

a. Conscience Laws

Comment: Some commenters supported revising the Section 1557 Rule to explicitly identify the Federal public consensus that conscience statutes reflect, in order to ensure appropriate protection for all civil rights. Some noted that the Coats-Snowe and Church Amendments were passed by Congress and signed into law on a bipartisan basis, reflecting explicit protections from discrimination on the Federal, State, or local level if healthcare providers or hospitals seek to be exempted from participation in the performance or training for abortions.

Some commenters supported including references to conscience and religious freedom laws in § 92.6(b), stating that protecting the conscience rights of healthcare providers also protects patients by protecting trust between patients and providers, and allowing providers who entered healthcare on the basis of moral convictions to serve those who are ill consistent with that ethic. They also stated that providers must exercise professional judgment as to what constitutes the best interest of the patient. Commenters stated that respect for the autonomy of the patient should not be misconstrued to create coercive obligations on providers overriding the best interest of the patient. Some stated that the 2016 Rule resulted in a “Hobson’s choice” of options for certain providers, who were required under the rule to either violate their ethical pledges to Do No Harm or their longstanding oaths as physicians, or comply with the 2016 Rule and be forced to perform abortions. Some commenters also suggested that if those

providers complied with laws like Title VII and conscience laws that require religious accommodation, they could risk noncompliance with the 2016 Rule, or vice versa. Some of those commenters contended that coercing providers to compromise their moral integrity negatively impacts both provider and patient, and ultimately hurts the provider’s ability to provide patient care. If facing the threat of coercion, such commenters said, providers will continually face escalating moral dilemmas in the practice of their job, resulting in stress and burnout in a time when physician shortages are already increasing.

Other commenters opposed the language in § 92.6(b), saying that the proposed rule construes the Federal conscience protections more broadly than existing law allows. They contended conscience protections and religious liberty are meant for individuals, not entities, and that healthcare systems and entities cannot have the right of conscience, because the notion of conscience is limited to individuals. Some commenters also recommended that instead of removing gender identity and termination of pregnancy language and having the language in § 92.6(b) concerning conscience and religious freedom statutes, the Department should merely insert a narrow religious exemption, for they asserted that preventing discrimination on the basis of gender identity or termination of pregnancy is more critical than religious freedom rights, which should be more heavily scrutinized for pretextual discrimination. Other commenters stated that conscience and religious protections under the current statutes are sufficient and incorporating conscience or religious exemptions is unnecessary. Some opposed referring to the Coats-Snowe Amendment in § 92.6(b), saying that it would allow healthcare providers to decline to make medical care available to any patient based on personal beliefs. Some added that the Department does not have the authority to interpret statutes such as the Coats-Snowe Amendment to limit or supersede Section 1557, which should be seen as controlling law. One commenter stated that Federal conscience statutes are not applicable to the ACA because they are not mentioned in the ACA.

Response: Section 1557 and the ACA did not repeal any Federal conscience law. Indeed, ACA § 1303 specifically provides that “[n]othing in [the ACA] shall be construed to have any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to

provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.” 42 U.S.C. 8023(c)(2). At the time of its passage, the President stated that “[u]nder the [ACA], longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact and new protections prohibit discrimination against healthcare facilities and healthcare providers because of an unwillingness to provide, pay for, provide coverage of, or refer for abortions.”²⁵⁹ New law is to be interpreted consistently with existing law wherever possible, and the Department sees no conflict between Section 1557 and preexisting Federal conscience statutes.

This final rule emphasizes that the Section 1557 regulation will be implemented consistent with various statutes enacted by Congress, including conscience and religious freedom statutes. This should not be a controversial statement, nor should it even be necessary to add, as the Department is always obligated to comply with relevant Federal statutes. But the fact that so many commenters found this provision objectionable is itself a reminder of why such a provision is needed. The fact that the 2016 Rule was the subject of litigation and injunctive relief, in part because of plaintiffs’ claim that the 2016 Rule did not clearly state that it would be enforced consistent with conscience and religious freedom statutes, is also a reason the Department believes it is appropriate to make the issue clearer in this final rule. This final rule does not purport to construe the statutes referenced in this section, so it cannot be construing them too broadly (or too narrowly). It would be inappropriate to replace § 92.6(b)’s language with a religious exemption, whether narrow or broad, because § 92.6(b) neither adds to nor takes away from the conscience and religious freedom statutory language that Congress has enacted.

Commenters who discuss the gender identity and termination of pregnancy provisions of the 2016 Rule in this context are confusing two different issues. As stated above, this final rule eliminates the 2016 Rule’s provisions related to gender identity for numerous

²⁵⁹ Executive Order 13535, “Patient Protection and Affordable Care Act’s Consistency with Longstanding Restrictions on the Use of Federal Funds for Abortion” (March 24, 2010).

legal and policy reasons that have nothing to do with conscience protection, and it eliminates the 2016 Rule's provisions on termination of pregnancy because they failed to incorporate Title IX's abortion-neutrality language (which goes much farther than any mere protection for individual conscientious objectors). In neither case could the Department's concerns have been adequately addressed by permitting individuals to claim a conscientious exemption from those objectionable provisions.

Comment: Many providers with conscientious or religious concerns stated that their medical judgment is based upon a review of the clinical evidence, and that medical ethics requires that they act in accordance with their best medical judgment. For example, some commenters contended that they have practices, such as in the obstetrics and gynecology field, which are specialized to the biological sex of females based on a binary distinction between males and females. Others had objections because of their moral and religious convictions concerning specific procedures that they sincerely believed, both in their medical judgment and ethically, would endanger the health and wellbeing of a person.

Response: By respecting medical professionals' judgment, the Department protects their right and responsibility to follow medical ethics in treating patients to the best of their ability. In their objections to abortion, sex-reassignment procedures, or other treatments covered by the 2016 Rule, some providers assert that not only their medical judgment but also their conscientious or religious beliefs would be burdened by such procedures. The Department believes that the best way to avoid such burdens on conscience is, instead of requiring individual objectors to assert claims under RFRA or other applicable laws, to avoid regulatory requirements that would have forced them to provide such procedures in the first place, as well as to ensure that remaining requirements are interpreted consonant with the applicable Federal conscience statutes.²⁶⁰ This will protect both providers' medical judgment and their consciences, thus helping to ensure that patients receive the high-quality and conscientious care that they deserve.

Comment: Some commenters argued that religious or conscience exemptions were used as a pretext to conceal animus against LGBT individuals.

Commenters expressed concerns that the proposed rule would improperly prioritize conscience and religious freedom rights over LGBT rights or civil rights in general. However, others, such as hospital associations that expressed support for care regardless of gender identity and sexual orientation, explained that they also support appropriate protections for the reasonable accommodation of a nurse or other provider who may assert a sincere conscientious objection to participating in a particular medical procedure. Other providers stated that the exemption they seek is from providing certain treatments, not from treating certain patients. Some submitted their hospital nondiscrimination policies, contending those policies do not include blanket denial of healthcare treatment for LGBT individuals, and in many cases expressly prohibit discrimination on the basis of gender identity or sexual orientation, but that they nonetheless seek limited exemptions on the basis of sincerely held religious and moral convictions. Some individual, institutional, and religious groups affiliated with healthcare providers also provided comments stating that both in policy and in practice, they have never refused to care for a patient on the grounds of their identity as an LGBT individual. They stated that they object to being required to perform services that violate sound medical judgment, ethical convictions, or religious beliefs about the dignity of human beings. Commenters also submitted surveys finding healthcare professionals experienced pressure, coercion or punishment for not participating in training, performing a procedure, or writing a prescription when they had medical or scientific objections.

Response: The Department recognizes that members of the public hold different opinions concerning conscience and religious freedom laws and their interplay with various health contexts, including with respect to LGBT concerns. This final rule does not, however, create any new conscience or religious freedom exemptions beyond what Congress has already enacted.

Comment: Some commenters contend that women of color are more likely to rely on religious hospitals to receive care, and thus women of color will be more likely to be affected by religious exemptions that allow religious hospitals to deny certain reproductive care. Others opposed inclusion of references to conscience and religious freedom laws, stating that the danger of losing Federal funds is the only incentive for covered entities to offer more abortion, contraception,

sterilization, gender identity affirming, or sex reassignment services. Other commenters stated that conscience laws were intended to protect health professionals from precisely that form of government coercion.

Some commenters stated that the proposed rule, in particular concerning the Church Amendments, 42 U.S.C. 300a-7, is inconsistent with EMTALA, because the conscience exemptions would deny emergency and stabilizing care, including with respect to abortion or sterilization. Other commenters stated that the rule is consistent with EMTALA, because EMTALA requires protection of the "unborn child."

Response: The Department is not aware of any instance to date where a facility required to provide emergency care under EMTALA was unable to do so because of objections protected by the Church Amendments. This final rule does not adopt any stance on how hypothetical conflicts between the Church Amendments and EMTALA ought to be resolved. The Department intends to read every law passed by Congress in harmony to the fullest extent possible, so that all laws are given their fullest possible effect. Commenters' other policy concerns about the possible healthcare effects of the conscience laws are among the many complicated factors that Congress had to balance in the texts of the separate statutes, and it is not the Department's job to overturn the results of that legislative process.

Comment: One commenter compared the proposed rule with the 2019 Conscience Rule and alleged that the Department's recent actions of decreasing protections for patients and increasing protections for providers run contrary to actual public sentiment. The commenter alleged that between 2008 and January 2018, the Department received fewer than 50 complaints regarding violations of Federal religious or conscience statutes while receiving 30,000 complaints of other civil rights discrimination in 2017 alone. Other commenters stated that the 2019 Conscience Rule violates EMTALA, and results in the denial of transition-related surgeries or abortion services in emergencies, because conscience statutes allow exemptions from performance of sterilizations or abortions. Commenters also recommended that the Department delay finalizing the proposed rule pending the outcome of litigation challenging the 2019 Conscience Rule, in order to provide clarity and finality, and to reduce litigation risk as regards the construction of Section 1557 with conscience statutes.

²⁶⁰ See *California v. Azar*, at *24 ("HHS acted well within its authority in deciding how best to avoid conflict with the Federal conscience laws.").

Response: This final rule is separate from the 2019 Conscience Rule. It does not implement that rule, and it does not implement the statutes implemented by that rule. Several courts have vacated the 2019 Conscience Rule before its effective date, but none of those courts issued any order against the conscience statutes themselves,²⁶¹ which the Conscience Rule sought to implement and which this final rule references. Because this final rule does not refer to or rely on the 2019 Conscience Rule, there is no reason to delay finalization of this rule pending further litigation over the 2019 Conscience Rule.

b. Religious Freedom Restoration Act

Comment: Some commenters said that the proposed rule's inclusion of the Religious Freedom Restoration Act ("RFRA") in § 92.6(b) was unclear and confusing. Others said that it should be excluded because it would allow providers to deny needed healthcare. Other commenters supported inclusion of RFRA, agreeing that it is an important protection for religious conscience from government-imposed burdens. Commenters also pointed out that the Federal government has clearly articulated its commitment to RFRA and religious freedom laws under a recent executive order²⁶² and the subsequent Attorney General Memorandum²⁶³ to executive departments and agencies that "Congress has taken special care with respect to programs touching on abortion, sterilization, and other procedures that may raise religious conscience protections."²⁶⁴ One commenter supported the Department's explicit acknowledgment that Section 1557 is subject to RFRA, stating that religious organizations have had to repeatedly go to court to vindicate their conscience rights against the Department's enforcement of the 2016 Rule. Others said that referring to RFRA accurately reflects statutory text and Congressional intent, and would correct a legal misinterpretation of Section 1557 that has been recognized as such by the *Franciscan Alliance* court.

Response: Congress explicitly stated that RFRA applies to "all Federal law, and the implementation of that law,

whether statutory or otherwise, and whether adopted before or after November 16, 1993 . . . unless such law explicitly excludes such application by reference to this chapter."²⁶⁵ Section 1557 does not explicitly exclude such application, so the Department is bound to enforce Section 1557 in compliance with RFRA. The Department agrees with the court in *Franciscan Alliance* that particular provisions in the 2016 Rule violated RFRA as applied to private plaintiffs.²⁶⁶ In order to ensure that Section 1557 regulations are now interpreted consistently with, and implemented in compliance with, RFRA, the Department considers it appropriate to specify this explicitly.

Comment: Some commenters stated that the text of the Section 1557 statute does not contain a religious exemption, and therefore asked the Department not to include a religious exemption, either explicitly or by reference in § 92.6(b). Other commenters stated that exemptions on religious bases should be blanket exemptions, not case-by-case exemptions as outlined in RFRA.

Response: This final rule does not craft a religious exemption to Section 1557. Congress has already created various religious and conscience protections in healthcare by enacting several statutes, including RFRA, healthcare conscience statutes, and the religious organization exception in Title IX. This final rule simply states that the Section 1557 regulation will be implemented consistent with those statutes.

c. Title IX

Comment: Some commenters opposed including reference to the Title IX statutory religious exemption in § 92.6(b). They said that Section 1557 does not require or authorize Title IX religious or abortion exemptions, because these are limited to educational institutions, and are improper in the healthcare context. Others expressed concern that Section 1557 and Title IX would be subject to exemptions that HHS does not apply to its rules enforcing Title VI.

Other commenters stated that it is unnecessary and unwise to change the standard for the religious exemption under Title IX, and pointed to the legislative history of Title IX, where the Conference Committee rejected an amendment proposed by Senator Hatch to loosen the standard for the religious

exemption. Commenters stated that § 92.101(c) of the 2016 Rule took an inconsistent analysis by failing to incorporate Title IX's religious and abortion exemptions, despite incorporating exemptions from the other three Federal civil rights laws referenced in Section 1557.

Still other commenters stated that the Title IX exemption should not apply broadly to large religious institutional healthcare facilities, or that conscience protections and religious liberty cannot apply to institutions like hospitals or healthcare systems because they cannot have the right of conscience. They suggested that conscience is limited to individuals and that an institution is not a person. Other commenters disagreed and pointed to legislative history to recognize that the protections under Title IX's religious exemption are not just for individuals but for institutions.

Response: The text of Title IX applies its religious exemption to institutions, so there should be no question that religious exemptions can apply to institutions as well as individuals.²⁶⁷ As discussed above regarding termination of pregnancy, the *Franciscan Alliance* court vacated portions of the 2016 Rule for failing to incorporate Title IX's exemption for religious institutions. More generally, the Supreme Court in *Burwell v. Hobby Lobby* held that RFRA can apply to for-profit corporations. 573 U.S. 682 (2014). And that holding parallels other Supreme Court precedent making clear that organizations may engage in exercises of religion protected by the First Amendment. *See, e.g., Masterpiece Cakeshop, Ltd. v. Colo. Civil Rights Comm'n*, 138 S. Ct. 1719, 1732 (2018); *Hosanna-Tabor Evangelical Lutheran Church & Sch. v. EEOC*, 565 U.S. 171, 199 (2012); *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 525–26, 547 (1993).

Under the Civil Rights Restoration Act amendments to Title IX, the Title IX religious exemption is no longer limited to educational institutions controlled by religious organizations: Any educational operation of an entity may be exempt from Title IX due to control by a religious organization.²⁶⁸ Section 1557

²⁶¹ *See New York v. United States Dep't of Health & Human Servs.*, 414 F. Supp. 3d 475 (S.D.N.Y. 2019); *City & Cty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001 (N.D. Cal. 2019); *Washington v. Azar*, No. 2:19-CV-00183-SAB, 2019 WL 6219541 (E.D. Wash. Nov. 21, 2019).

²⁶² Executive Order 13798 on Promoting Free Speech and Religious Liberty, 82 FR 21675 (May 4, 2017).

²⁶³ Memorandum of the Attorney General (Oct. 6, 2017), <https://www.justice.gov/opa/press-release/file/1001891/download>.

²⁶⁴ *Id.*

²⁶⁵ 42 U.S.C. 2000bb–3.

²⁶⁶ *Franciscan Alliance*, 2019 WL 5157100 at *9 ("[T]he Court holds that the Rule, which expressly prohibits religious exemptions, substantially burdens Private Plaintiffs' religious exercise in violation of RFRA.")

²⁶⁷ *See* 20 U.S.C. 1681(a)(3) ("this section shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization"); 20 U.S.C. 1687(4) (excluding "any operation of an entity which is controlled by a religious organization if the application of section 1681 of this title to such operation would not be consistent with the religious tenets of such organization").

²⁶⁸ *Id.*

incorporates the statutory scope of Title IX, so it is appropriate for this rule to incorporate the Title IX statutory language concerning religious institutions and abortion neutrality. Although much of Title VI case law can be applied to Title IX situations, the parallel is not perfect because Title IX contains several important statutory exemptions that are absent from Title VI. These are mentioned above in the section on discrimination on the basis of sex.²⁶⁹

Comment: Commenters stated that adding the Title IX exemption for religious entities violates the Establishment Clause, because it would force third parties to subsidize or bear the costs of religious exercise, citing *Cutter v. Wilkson*, 544 U.S. 709 (2005), *Lee v. Weisman*, 505 U.S. 577 (1992), and *Estate of Thornton v. Caldor, Inc.* 472 U.S. 703 (1985). Commenters indicated that religious exemptions must take an adequate account of the burdens a requested accommodation may impose on nonbeneficiaries. Commenters similarly suggested that the rule's requirement that the Section 1557 rule be implemented consistent with RFRA would violate the Establishment Clause and should be limited to instances where no third party is harmed by application of RFRA.

Response: Neither RFRA (as applied to Federal government actions), nor Title IX's statutory exemptions, have ever been held unconstitutional by the Supreme Court. The Court has upheld Title VII's statutory exemption for religious organizations,²⁷⁰ and has denied that statutory exemptions of this type violate the Establishment Clause.²⁷¹ The Department will comply with all relevant court rulings.

d. Other Laws and Cases

Comment: The Department received comments supporting the express mention of Section 1303 of the ACA²⁷² in proposed § 92.6. These commenters contended that this helps clarify the prohibition on mandating QHPs to provide abortions, and that it could not have been Congress's intent to mandate abortion coverage in Section 1557. Section 1303 expressly leaves it up to issuers of health plans to decide not to cover abortion. Other comments stated that Section 1303 should not be expressly mentioned in this rule and that termination of pregnancy should remain as a prohibited basis of discrimination under the Section 1557 rule, notwithstanding Section 1303.

Response: In Section 1303, Congress specified that nothing in the ACA (therefore including Section 1557) "shall be construed to have any effect on Federal laws regarding (i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion" (emphasis added). The Department considers it appropriate to finalize § 92.6 to indicate that the Section 1557 regulation will be implemented consistent with Section 1303, as that provision is relevant to the interpretation of the Federal laws that Section 1557 incorporates by reference.

Comment: The Department received comments from State public officials raising concerns about the 2016 Rule's constitutionality. State public officials contended that the 2016 Rule violated the Spending Clause because the Federal government did not provide adequate notice by clear statement and opportunity to agree to the Section 1557 Rule's new conditions on receipt of Federal financial assistance. States also raised objections under the Eleventh Amendment to the Department-initiated Section 1557 enforcement actions. States identified their obligation to protect the First Amendment rights to free exercise of religion of their citizenry. However, these State commenters noted that the proposed rule's removal of the definition of "on the basis of sex," and the addition of the religious and abortion exemptions, would address these concerns.

Other commenters stated that when the Department said in the 2019 NPRM that State and local entities are better suited than the Federal government to

address gender identity discrimination, this was contrary to constitutional law principles and undermined the right to be free from discrimination.

Response: The Department is not aware of any Supreme Court precedent that would call into question the constitutionality of its reasoning about federalism as laid out in the 2019 NPRM.²⁷³ The Department believes that this final rule resolves the concerns States had about the 2016 Rule's constitutionality.

Comment: Some comments from State public officials stated that the 2016 Rule conflicted with State laws on religious accommodations and independent medical judgment of healthcare providers. A different group of State public officials submitted a separate joint comment stating that their States' civil rights legislation and/or regulations prohibited discrimination on the basis of gender identity or sexual orientation, and that the proposed rule would remove the consistency of their laws with the 2016 Rule. They argued that State insurance agencies acted first to promulgate regulations after passage of Section 1557 in 2010, assuming that Section 1557 prohibited gender identity discrimination. Some States also said that the proposed rule's incorporation of Federal conscience statutes would result in conflict with State laws, or with other Department rules requiring covered entities to provide care to all (e.g., vaccination care).

Some States said that as employers they had difficulty resolving religious accommodation laws with Section 1557. Others stated they had no difficulties resolving consumer complaints of discrimination on the basis of gender identity.

Response: The Department agrees that States have a public interest in enforcement of their statutes, including conscience and religious freedom statutes. This final rule respects Federalism: It neither interferes with State laws on conscience protections and medical judgment, nor does it interfere with State laws that provide additional protections (so long as these do not violate other Federal statutes). The rule also explicitly provides that Section 1557 will not be taken to supersede State laws that provide additional protections against discrimination on the enumerated grounds. The Department is not aware of actual, as opposed to hypothetical, conflicts between the statutes incorporated here and other laws or

²⁶⁹ 20 U.S.C. 1681(a)(6)(B); 34 CFR 106 *et seq.*

²⁷⁰ *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 338–40 (1987); see also *Walz v. Tax Comm'n. of City of New York*, 397 U.S. 664 (1970) (upholding the constitutionality of a state's statutory property tax exemption for religious organizations); *Id.* at 675 ("The grant of a tax exemption is not sponsorship since the government does not transfer part of its revenue to churches but simply abstains from demanding that the church support the state. No one has ever suggested that tax exemption has converted libraries, art galleries, or hospitals into arms of the state or put employees 'on the public payroll.' There is no genuine nexus between tax exemption and establishment of religion.").

²⁷¹ *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints v. Amos*, at 336–37 ("We agree with the District Court that this purpose does not violate the Establishment Clause. . . . A law is not unconstitutional simply because it allows churches to advance religion, which is their very purpose."); *Id.* at 339 ("It cannot be seriously contended that [Title VII's statutory exemption] impermissibly entangles church and state; the statute effectuates a more complete separation of the two and avoids the kind of

intrusive inquiry into religious belief that the District Court engaged in in this case.").

²⁷² 42 U.S.C. 18023.

²⁷³ See 84 at 27857 (2019 NPRM discussion of "Sensitive Balancing of Competing Interests at the Local Level" at Part g).

regulations that the Department enforces.

Comment: A commenter supported including the reference to Section 1553 of the ACA in § 92.6 in order to protect nurses who have objections to participating in assisted suicide, promote trust in the nurse-patient relationship, and keep the profession open to candidates who want to serve as nurses but object to participation in assisted suicide.

Commenters supported the proposal's specification that the proposed regulation not be applied in a manner that conflicts with or supersedes exemptions, rights, or protections contained in several civil rights statutes, such as the Architectural Barriers Act of 1968, the Americans with Disabilities Act of 1990 (as amended by the Americans with Disabilities Act Amendments Act of 2008), and Section 508 of the Rehabilitation Act of 1973.

Some commenters requested that the word "obligations" be added in order to specify that the proposed regulation not be applied in a manner that conflicts with or supersedes the exemptions, rights, protections or obligations contained in several civil rights statutes. This addition would help clarify that this consideration is intended to help reduce redundancy, compliance burdens, and confusion for healthcare providers.

Response: The Department appreciates all these comments in support of the proposed rule. The Department declines to add the word "obligations," as the final rule's language adequately addresses its interaction with other civil rights statutes.

Comment: One commenter noted that a number of provisions in the proposed rule seem to contradict portions of the recent Conscience Rule published by the Department.²⁷⁴ In particular, this proposed rule eliminates and narrows definitions advanced by the 2016 Rule, while the Conscience Rule expands definitions and protections. This proposed rule seeks to drastically cut costs of enforcement by eliminating notice and taglines requirements and other costs for providers, while the Conscience Rule will impose new costs on providers and individuals. Finally, this proposed rule and the Conscience Rule use different definitions to define health programs and activities.

Response: The 2019 Conscience Rule and this final rule rely on different statutes, and different underlying regulations for those statutes, so it is not surprising that there should be

differences between their respective definitions and protections. The four civil rights statutes underlying Section 1557 have implementing regulations containing appropriate definitions, protections, and enforcement mechanisms. As explained herein, the Department has now deemed most of the parallel provisions in the 2016 Rule to be unnecessary, superfluous, or unduly burdensome. Therefore the Department considers it appropriate to finalize a Section 1557 rule that is shorter than the 2016 Rule and relies more substantially on those underlying regulations. In contrast, the 2019 Conscience Rule (which has been vacated and is subject to pending litigation) modified previous regulations that are only three sentences long, and that lack the kinds of definitions and enforcement mechanisms found in regulations implementing other civil rights laws enforced by the Department. In promulgating the 2019 Conscience Rule, the Department concluded more extensive regulations were needed in the absence of existing regulations containing such provisions.

Comment: One commenter stated that the proposed rule's changes to the relationship to other laws section at § 92.6 are contrary to the requirements of Section 1557, because the 2016 Rule stated that neither it nor Section 1557 would apply a lesser standard than Title VI, Title IX, Section 504, or the Age Act. In contrast, the proposed rule expressly states that application of the proposed rule will not be required if the proposed rule violates, departs from, or contradicts a number of other Federal civil rights laws.

Response: The Department seeks to give all laws their fullest possible effect. It does not believe that the other laws referenced at § 92.6 are generally in conflict with Title VI, Title IX, Section 504, or the Age Act, except to the extent that some of them (e.g., RFRA) may be specifically designed to limit the applicability of other Federal laws and governmental actions.

e. Summary of Regulatory Changes

For the reasons described in the proposed rule and having considered the comments received, the Department finalizes § 92.6 and repeals §§ 92.2(b) and 92.3 of the 2016 Rule without change.

C. Section 1557 Regulation, Subpart B: Specific Applications to Health Programs or Activities (Sections 92.201–92.205 of the 2016 Rule)

The Department requested comment on the proposed retention and modification of the provisions in

Subpart B of the Section 1557 regulation, which imposes specific requirements on covered entities as regards individuals with LEP or disabilities.

(1) Meaningful Access for Individuals With Limited English Proficiency (45 CFR 92.101)

The Department proposed § 92.101(a), which states that any entity operating or administering a health program or activity subject to the Section 1557 regulation is obligated to take reasonable steps to ensure meaningful access to such programs or activities by LEP individuals. It also proposed § 92.101(b), which states that OCR may assess how an entity balances the following four factors:

- (1) The number or proportion of LEP individuals eligible to be served or likely to be encountered in the eligible service population;
- (2) the frequency with which LEP individuals come in contact with the entity's health program, activity, or service;
- (3) the nature and importance of the entity's health program, activity, or service; and
- (4) the resources available to the entity and costs.

Section § 92.101(b) retains many of the 2016 Rule's provisions related to access for LEP individuals. It removes definitions of the terms "qualified bilingual/multilingual staff" and "individual with limited English proficiency," but the 2019 NPRM expressed the Department's commitment to interpreting those terms naturally and consistently with the 2016 Rule.²⁷⁵ It also repeals the 2016 Rule's definition of "national origin."

The Department requested comment on whether the proposed retention of some provisions that impose requirements on covered entities under the Section 1557 Regulation (which govern health programs or activities), but not on entities that only receive HHS funding for human services, would cause problems or confusion, and (if so) whether this might warrant amendments to the Department's Title VI regulation.

Comment: In response to the Department's request for comment concerning possible amendments to the underlying civil rights regulations, some commenters said that they were unable to provide meaningful comments without HHS first providing explanations and rationale for any proposed changes, and that unanticipated changes could not be

²⁷⁴ 45 CFR part 88.

²⁷⁵ 85 FR 27860–61, 27866.

made in a final rule without first giving the public an opportunity to comment on those proposed changes.

Response: The Department did not propose changes to regulations other than those finalized here, but simply invited comment on whether to consider doing so. In this final rule, the Department does not implement any such changes, and in this respect finalizes the proposed rule without change. The Department here finalizes only those changes proposed in the 2019 NPRM (with minor and primarily technical changes to these).

Comment: Some commenters opposed the proposed rule's revisions to the requirements for meaningful access for LEP individuals, arguing that they weaken nondiscrimination requirements. These commenters noted that instead of requiring covered entities to take reasonable steps to provide meaningful access for *each* "LEP individual eligible to be served or likely to be encountered," the proposed rule only requires covered entities to take steps to ensure meaningful access for "LEP individuals" generally. These commenters contend that this change will result in a number of LEP individuals unable to access healthcare, and will contribute to discrimination and to healthcare disparities for LEP individuals. Many commenters stated that lack of understanding in a medical setting could cause harm and possibly death to patients with LEP. One commenter emphasized the facilitative role that interpreters play to decrease risk associated with miscommunication between patients and providers. A commenter expressed concerns that healthcare services would dramatically decrease for individuals with LEP who are unable to access an interpreter. Another commenter objected to the notion that oral interpretation for patients would not be required. Some commenters also oppose the replacement of the 2016 Rule's two-factor test with a four-factor test. One commenter recommended replacing the term "reasonable" in the Department's LEP Guidance meaningful access standard with the term "all," saying that the word "reasonable" leaves too much room for ambiguity in its application.

Response: The 2016 Rule imposed a stringent requirement on covered entities to take reasonable steps to provide meaningful access to each LEP individual eligible to be served or likely to be encountered. This provision could potentially be interpreted to require a covered entity to provide language assistance services to every LEP individual it comes into contact with. This final rule instead follows DOJ's

longstanding LEP guidance (under Executive Order 13166), and HHS's corresponding LEP guidance from 2003, by saying that a covered entity under Title VI must take reasonable steps to ensure meaningful access to its programs or activities by LEP individuals.²⁷⁶ Adopting this language would apply the same standard to both health and human services programs within the Department, and would conform to the other Federal agencies that follow DOJ's LEP Guidance, consistent with its civil-rights coordinating authority. Because Section 1557 incorporates the enforcement mechanisms available under Title VI (which encompasses LEP status under *Lau v. Nichols*),²⁷⁷ it is appropriate for this final rule to adopt the Title VI standard requiring reasonable steps to ensure meaningful access.

This final rule also incorporates the four-factor test found in the DOJ LEP Guidance and reiterated in the Department's own 2003 LEP Guidance. That test is "designed to be a flexible and fact-dependent standard,"²⁷⁸ and is meant to strike a balance that ensures meaningful access by LEP individuals to critical services while not imposing undue burdens on small businesses, small local governments, or small nonprofits. As the 2019 NPRM made clear, an individualized case-by-case assessment of the four factors is the starting point for exercising the Department's enforcement discretion in language access cases.²⁷⁹

This final rule retains, and the Department will vigorously enforce, the underlying legal standard of Title VI: Recipients are prohibited from utilizing criteria or methods of administration which have the effect of subjecting individuals to discrimination on the basis of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the program with respect to individuals on the basis of their race, color, or national origin. Entities that utilize such criteria or methods of administration have failed to take reasonable steps to ensure meaningful access to their programs by individuals with LEP and are operating their programs in violation of this final rule's

prohibition against discrimination on the basis of national origin. All covered entities remain obligated to submit assurances that they will comply with Title VI and all other relevant civil rights law.²⁸⁰

The language access provisions in this final rule are consistent with Title VI enforcement mechanisms and with the Department's longstanding guidance. Title VI enforcement mechanisms are broadly known to the regulated community, and the HHS LEP Guidance has been effective in helping covered entities comply with the statute and implementing regulations. The Department regards the four-factor test, employed since 2003, as the best way of balancing the relevant factors in ensuring nondiscrimination on the basis of national origin. Under this final rule, the Department's LEP Guidance will help covered entities assess their programs using the four factors to ensure meaningful access to their programs by individuals with LEP. By eliminating confusion, inconsistency, redundancy, and unnecessarily burdensome compliance costs, this final rule applies proven enforcement mechanisms and guidance to ensure access to covered programs by individuals with LEP.

Comment: Commenters stated that the proposed rule significantly reduces the administrative burden placed on providers. For example, the proposed rule will allow retail pharmacies to provide patients with better quality of care in a more efficient manner. Another comment emphasized that under the 2016 Rule, providers are required to physically post the information at their facilities, on their websites, and in any "significant" publications and communications. This example underscored that the term "significant" has never been defined by OCR, which has resulted in providers using taglines notices in nearly every document provided to patients. This practice was described as administratively burdensome and counterproductive, because patients already receive numerous notices mandated by the Department. Another commenter expressed support for the proposed rule's empowerment of individual entities to take reasonable steps to ensure meaningful access.

Response: The Department agrees, and recognizes the burdens imposed by the 2016 Rule's requirement to post notices and taglines in all significant communications and publications, as well as by the difficulty of determining the meaning of "significant" with

²⁷⁶ See 67 FR 41455 (June 18, 2002) (DOJ Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons).

²⁷⁷ 414 U.S. 563 (1974).

²⁷⁸ 68 FR 47314 (Aug. 8, 2003) (HHS Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons).

²⁷⁹ 84 FR 27865 (June 14, 2019).

²⁸⁰ See 84 FR 27860.

respect to the numerous and diverse types of programs covered by this final rule. These requirements were difficult for covered entities to implement due to different and overlapping language access requirements imposed by the Federal government and by many States.²⁸¹ Stakeholders have informed the Department that the repetitive nature of these requirements dilutes the messages contained in significant communications to the point that some recipients may be disregarding the information entirely.²⁸² In addition, many beneficiaries do not want to receive extra pages of information they have seen many times before, due to environmental concerns or annoyance.²⁸³ Most significantly, the Department has found scant evidence to demonstrate that repeatedly mailing all beneficiaries of Federal and other health programs taglines with 15 or more languages is an efficient use of covered entities' language access resources when the overwhelming majority of

beneficiaries speak English.²⁸⁴ Savings from the notice and taglines requirements changes are described in more detail in the Regulatory Impact Analysis.

Comment: Some commenters stated that the notices and taglines requirements of the 2016 Rule are burdensome, but that the Department should consult with stakeholders to determine how to most effectively and efficiently communicate with LEP individuals, rather than repeal the requirements.

Response: The Department consulted with the public before and since issuing policy guidance to recipients on compliance with the Title VI obligation to take reasonable steps to ensure meaningful access to their programs by individuals with LEP. The Department also provided stakeholders with an opportunity to comment on the proposed rule during the public comment period.

Comment: The Department received comments opposing the proposed rule's revised § 92.101, which requires covered entities to take reasonable steps to ensure meaningful access to its programs or activities by individuals with LEP. Commenters asserted that the proposed change is contrary to congressional intent because the language in Section 1557 is clear that "an individual shall not" be subject to discrimination on the prohibited grounds. Others stated that the proposed § 92.101 inappropriately changes the Section 1557 regulation language and shifts the focus of the regulation from an individual's rights to the covered entity's programs or activities, thus weakening meaningful access and running contrary to the text of Section 1557.

Still others recommended that—through sub-regulatory guidance—the Department should communicate to providers the flexibility of the LEP access requirement.

Response: This final rule fully retains all protections offered by Section 1557, and it does not shift any focus from an individual's rights to the covered entity's programs or activities. It ensures that covered entities do not use their programs or activities to discriminate on the basis of any individual's national origin, which includes (under *Lau's* disparate impact analysis) requiring

those entities to provide reasonable access to LEP individuals.

Comment: The Department received comments asserting that language assistance is necessary for individuals with LEP to access Federally funded programs and activities in the healthcare system. Several commenters argued that adequate translation services are a civil right and an important tool for informing individuals with LEP of their healthcare rights. One commenter also expressed concern that informed consent is compromised when a language barrier prevents a patient from understanding what he or she is consenting to. Many commenters also said that individuals with LEP face unique challenges in healthcare that are mitigated by language access services, and that the proposed rule might weaken access by patients with LEP to quality healthcare, resulting in patients' avoiding or postponing the medical care they require out of fear of discrimination or mistreatment due to their national origin or the language they speak.

Response: The Department strongly agrees that language assistance is often vital for ensuring access to Federally funded programs and activities in the healthcare system by individuals with LEP. The Department believes this final rule highlights its commitment to ensuring that individuals with LEP receive language access services that are appropriate under the circumstances and consistent with longstanding enforcement mechanisms and guidance. Accordingly, this final rule clarifies throughout § 92.101 that where language assistance services are required to be offered by a covered entity, they must be no-cost, timely, and accurate; that translators or interpreters provided in order to comply with the law must meet specific minimum qualifications, including ethical principles, confidentiality, proficiency, effective interpretation, and the ability to use specialized terminology as necessary in the healthcare setting; and that a covered entity may not require an individual with LEP to bring his or her own interpreter or rely on a minor child or accompanying adult to facilitate communication, except under limited exceptions. In addition, the Department expects that the cost savings estimated below resulting from repeal of notice and taglines requirements will, where applicable, free up resources that entities can use to provide more access to LEP individuals.

Comment: A commenter said that the proposed rule weakens system-wide standards governing access to language assistance services and will

²⁸¹ E.g., 42 U.S.C. 300gg–15(b)(2) and 300gg–19(a)(1)(B) (requiring standards for ensuring that the Summaries of Benefits and Coverage and certain notices are provided in a culturally and linguistically appropriate manner); 42 U.S.C. 1396d(p)(5)(A) (requiring HHS to distribute to States an application form for Medicare cost-sharing in English and 10 non-English languages); 26 CFR 1.501(r)–4(a)(1), (b)(5)(ii) (requiring a hospital organization to translate certain documents, among other requirements, to qualify for a tax-exempt status with respect to a hospital facility); 42 CFR 422.2262(a)(1)–(2) and 422.2264(e) (setting forth Medicare Advantage marketing requirements, which include requiring Medicare Advantage organizations to translate marketing materials into non-English languages spoken by 5% or more of individuals in a plan service area); 423.2262(a)(1)–(2) and § 423.2264(e) (setting forth Medicare Part D marketing requirements, which include requiring Part D plan sponsors to translate marketing materials into non-English languages spoken by 5% or more of individuals in a plan service area); 45 CFR 155.205(c)(2)(iii)(A) (Marketplaces must post taglines on their websites and include taglines in documents "critical for obtaining health insurance coverage or access to health care services through a QHP"); 68 FR 47318 (Aug. 8, 2003)—Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (setting forth guidance on translating "vital" documents).

²⁸² See Aetna, "Member Reactions to 1557 Taglines" (Apr. 2017), available at <https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0002>; American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017), available at <https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0003>; Pharmaceutical Care Management Association (May 2, 2017), available at <https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0006>.

²⁸³ See Aetna (May 1, 2017), available at <https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0005>; Pharmaceutical Care Management Association (Mar. 27, 2017), available at <https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0007>; American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017), available at <https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0003>.

²⁸⁴ See Pharmaceutical Care Management Association (Mar. 27, 2017), available at <https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0007>; American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017), available at <https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0003>.

disincentivize the broader system from embedding and institutionalizing LEP services.

Response: The Department knows of no evidence to support this assertion and considers it an improbable one, as this final rule simply applies the longstanding and well-known enforcement mechanisms of Title VI that have proven effective over time in ensuring access by individuals with LEP to covered programs.

Comment: Commenters said that it would be beneficial if the Department contacted providers with educational documents outlining the requirements under the proposed rule.

Response: It is not Department practice to reach out to all covered entities individually upon every regulatory change. At the same time, OCR does engage in various kinds of outreach to the regulated community. The proposed rule was published in the **Federal Register** and publicized on OCR's website, and this final rule will be publicized similarly. The Department expects its changes to reduce confusion among covered entities. If OCR sees evidence that this final rule's changes are causing any new confusion, OCR will consider issuing relevant guidance and education.

Comment: The Department received comments opposing the elimination of the provision requiring the Director to consider, if relevant, whether an entity has developed and implemented an effective written language access plan appropriate to its particular circumstances. Commenters stated that language access plans are important for evaluating compliance with Section 1557 and for planning efforts to address the needs of LEP individuals.

Response: The HHS LEP Guidance continues to encourage recipients to produce language access plans, but does not require them, and offers assistance to help ensure that implementation provides meaningful access by individuals with LEP. DOJ's LEP Guidance also does not require entities to produce such a plan. This final rule brings the Department's LEP regulations into closer conformity with the DOJ guidance, while Departmental guidance continues to encourage covered entities to go beyond minimum regulatory requirements.

Comment: One commenter argued that the justifications related to costs and resource availability do not supersede the right to meaningful access for individuals with LEP. Another commenter objected to cost's being the primary determinant for compliance with the proposed rule.

Response: Cost is not the primary factor in the four-factor analysis; no single factor is determinative. The four-factor analysis does not supersede the right to meaningful access but rather helps determine when an entity has taken reasonable steps to secure that right.

Comment: Some commenters believe the four-factor analysis under § 92.101(b) is too broad, lacks clarity, does not ensure that translation and other language services are available under important medical circumstances, may require recipients to provide unnecessarily expensive services, and/or weakens recipient language access obligations to serve persons who speak infrequently encountered languages. Others said that the proposed rule does not require a medical provider to make any effort to secure translation services when a patient faces a dire medical condition. Others supported the proposed rule's changes, indicating they would provide more flexibility for covered entities while ensuring that LEP persons have meaningful access to services. Some indicated that covered entities should not be required to provide expensive forms of language assistance, such as video remote interpreting services.

Response: The Department agrees with commenters who state that the four-factor analysis is an appropriate way to allow flexibility for covered entities while ensuring meaningful access for LEP individuals. As to the specific hypothetical situations described by commenters, OCR will evaluate such situations as they are presented to OCR on a case-by-case basis. The fact-dependent nature of Title VI analysis makes it impossible to make pronouncements on such situations without all the relevant facts.

Comment: Some commenters requested that this final rule stipulate that health insurance plans are in compliance with the four-factor test if they incorporate either State LEP requirements or items 4–7 of the National Standards for Culturally and Linguistically Appropriate Services (CLAS).

Response: The ACA instructs the Department to apply to Section 1557 the enforcement mechanisms available under Title VI, which include mechanisms for enforcing language access cases. This final rule relies on longstanding Federal practice in enforcing Title VI; it is far from clear that the Department would have statutory authority to enforce the CLAS standards or State LEP requirements instead. Moreover, recipients that provide language assistance in

accordance with CLAS standards and State LEP requirements may still be utilizing other methods of administration that violate the final rule.

Comment: Some commenters suggested that administrative burden would be relieved by adopting uniform language access policies with other components in the Department like CMS, arguing that it would improve patient experiences and reduce errors.

Response: Because CMS program regulations are often implemented under different statutes than are civil rights regulations, and because LEP standards under Title VI have been subject to longstanding standards under DOJ and HHS guidance, the Department does not believe it is necessary at this time to adopt uniform language access standards across these different regulations. This final rule addresses regulations under Section 1557 and the civil rights statutes it incorporates.

Comment: Some commenters argued the proposed rule weakens the qualifications for language service providers by eliminating the words "qualified" and "above average familiarity with" from the proposed description of language interpreters and translators.

Response: This final rule does not weaken any qualifications for language service providers. It continues to use the term "qualified" six times in its regulatory text to describe "interpreters," "translators," or "staff" as relevant. As stated in the 2019 NPRM, this final rule eliminates the term "qualified" from the 2016 Rule only where it was redundant and clearly implied by the context—namely, a list of the translator's/interpreter's mandatory qualifications, a list that remains unchanged from the 2016 Rule.²⁸⁵ And the 2016 Rule expressly declined to include any reference to "above average familiarity."²⁸⁶

Comment: A commenter asserted that the proposed rule will adversely affect the patient-provider dialogue in addiction treatment programs, and underscored the importance of transparency in discussions about substance use history.

Response: The Department is not aware of any evidence to demonstrate this assertion, and believes that relying on the Department's underlying regulations and guidance will not result in such adverse effects.

Comment: Commenters expressed concern over the Department's proposal to remove requirements on video

²⁸⁵ 84 FR 27860, 27866.

²⁸⁶ 81 FR 31390–91.

interpreting quality standards as it relates to using video remote interpreting (VRI) services for LEP individuals or spoken language interpreting. Many commenters noted that most VRI services are done on the same equipment and through the same network and bandwidth for both spoken language and sign language, and that if these standards are removed for spoken language interpreters, there will be an unintended consequence of lower-quality VRI services for deaf and hard of hearing individuals. Other commenters noted that while they appreciated the incorporation of the ADA's definition of VRI, they opposed the removal of the technical and training requirements for the use of VRI for spoken language interpretation.

Some commenters recommended that all covered healthcare entities prioritize the use of on-site sign language interpreters, limit usage of VRI to specific situations, and maintain either a directory of local interpreters available for on-site work or a contract with an interpreter service provider to secure on-site interpreters when needed. Commenters offered detailed suggestions for regulations to limit VRI usage.

Response: In place of blanket requirements for VRI standards, this final rule adopts the four-factor analysis regarding access for LEP individuals, which will help covered entities balance competing considerations related to VRI quality standards. Where high-quality VRI is necessary to provide meaningful access to LEP persons, high-quality VRI will be required just as it was under the 2016 Rule. Furthermore, as is made clear in the next subsection (on proposed § 92.102), this final rule continues to hold covered entities to the ADA Title II standards for video interpretive services where these are needed for effective communication for deaf or hard of hearing individuals.

The Department requested comment on whether HHS's Title VI regulations at 45 CFR part 80 should be amended to address the *Lau v. Nichols*²⁸⁷ precedent.

Comment: A commenter stated that the Department's regulations implementing Title VI do not need to be amended to address *Lau v. Nichols* as HHS and DOJ have followed this Supreme Court precedent for decades.

Response: The Department agrees and will continue to enforce Title VI consistent with Federal law.

In reviewing § 92.101 and public comments, the Department observed that the proposed rule inadvertently

omitted the word "or" from the end of paragraph (b)(4)(ii)(A), concerning exceptions to the prohibition on using an adult accompanying an individual with LEP to interpret or facilitate communication. The "or" had been included in the parallel provision of the 2016 Rule at § 92.201(e)(2)(i); in the preamble to the proposed rule, the Department explained that it would apply those exceptions "[l]ike the current rule" (meaning as in § 92.201(e) of the 2016 Rule). 84 FR at 27866. To correct this, the Department finalizes § 92.101 with a technical change to insert "or" at the end of paragraph (b)(4)(ii)(A).

(2) Effective Communication for Individuals With Disabilities (45 CFR 92.102)

The Department proposed to retain the 2016 Rule's provisions on effective communication for individuals with disabilities. 84 FR at 27866–67.

Comment: A commenter suggested that each Section 1557 covered entity should simply comply with the standards that apply to each entity under the ADA, in order to reduce burden, confusion, and complexity.

Response: As a general matter, the Department does not view a covered entity's compliance with other Federal regulations, adopted with different requirements and for different purposes, as determinative of a covered entity's compliance with Section 1557.

Comment: The Department received comments expressing concern that the proposed rule would cause major harm to people with disabilities, affecting their access to effective healthcare, especially for those individuals in underserved and rural communities. Commenters suggested that because the current rule is working as it was intended, there is not sufficient reason to reopen it. Commenters argued that the ability to effectively communicate includes the individual patient as well as the patient's family/caregivers, and that the inability to effectively communicate can have significant adverse effects on an individual's access to healthcare. Other commenters expressed support for retaining the provisions of 45 CFR 92.202 (redesignated § 92.102), regarding effective communication for individuals with disabilities. Commenters noted that effective communication is a critical component to accessing and receiving healthcare and that often covered entities rely on communication methods that are the preference of the covered entity rather than the choice of the individual with a disability. Commenters stated that giving primary

consideration to the choice of aid or service requested by an individual with a disability helps to ensure effective communication and equal opportunity in the healthcare setting. Commenters commended HHS for holding all recipients of Federal financial assistance from HHS to the higher ADA Title II standards.

Response: Access to care continues to be a critical concern for the Department, and access to care clearly requires effective communication. The Department does not believe this final rule will impede individuals' access to care, but that instead it will assist individuals in understanding a covered entity's legal obligations and their own rights under Section 1557. In addition, the rule will assist the Department in complying with the mandates of Congress and further substantive compliance. Finally, because this final rule will lift unnecessary regulatory burdens on providers, the Department hopes that it will increase access to care, including in underserved and rural communities.

Comment: Commenters noted that the current regulation's language tracks the statutory text of Title I and Title III of the ADA and the regulatory language of Title II of the ADA, all of which protect against discrimination based on association or relationship with a person with a disability. They said that the proposed rule's elimination of the 2016 Rule's prohibition on associational discrimination will therefore create bewilderment concerning providers' responsibilities and individuals' rights. Commenters argued that deleting the language will create uncertainty and confusion regarding the responsibilities of providers and the rights of persons who experience discrimination, and inconsistencies with other regulatory requirements that entities are subject to, including the ADA and Section 504.

Response: As stated above, protections against discrimination on the basis of association will be available under this final rule to the extent that they are available under the incorporated civil rights statutes and their implementing regulations. The Department notes that courts have often relied on ADA statutory provisions in their handling of Section 504 claims.²⁸⁸

²⁸⁸ See Memorandum on Coordination of Federal Agencies' Implementation of Title II of the Americans with Disabilities Act and Section 504 of the Rehabilitation Act, Acting Assistant Attorney General (April 24, 2018); see, e.g., *Theriault v. Flynn*, 162 F.3d 46, 48 n.3 (1st Cir. 1998); *Henrietta D. v. Bloomberg*, 331 F.3d 261, 272 (2d Cir. 2003); *Helen L. v. DiDario*, 46 F.3d 325, 330 n.7 (3rd Cir. 1995); *Baird ex rel. Baird v. Rose*, 192 F.3d 462, 468 (4th Cir. 1999); *Delano-Pyle v. Victoria Cty., Tex.*, Continued

²⁸⁷ *Lau v. Nichols*, 414 U.S. 563 (1974).

Comment: Several commenters objected that the definition of auxiliary aids and services at proposed § 92.102(b)(1) excludes the term “Qualified” before “Interpreters” in subsection (i) and before “Readers” in subsection (ii), despite being part of the ADA definition at 28 CFR 35.104. Some Commenters strongly encouraged the Department to incorporate the ADA definition of “Qualified Reader” as follows: “Qualified reader means a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary.”²⁸⁹

Response: As stated above regarding § 92.101(a), this final rule eliminates the term “qualified” from the 2016 Rule only where it was redundant and clearly implied by the context. In this case, subsection (b)(2) clearly lists the mandatory qualifications for interpreters required under subsection (b)(1), and it adopts that list from the ADA definition at 28 CFR 35.104 and § 36.303(f). It would therefore be redundant to describe those interpreters in subsection (b)(1) as “qualified.” No definition of “Qualified Reader” appears in the 2016 Rule, so the Department is making no change in that regard. But the Department interprets this subsection naturally as requiring qualifications for readers that are similar to the expressly stated qualifications for interpreters.

Comment: Commenters argued that although the proposed rule claims to incorporate the definition of auxiliary aids and services from the regulations implementing Title II of the ADA, the rule as proposed changes the definition of auxiliary aids and services, omitting “acquisition or modification of equipment and devices; and other similar services and actions” from the list of examples of aids and services. Commenters noted that this proposed change will confuse providers and people with disabilities and will lead both groups to assume the list in the proposed rule is exhaustive. Commenters opposed these deletions and requested that the Department retain the definition of auxiliary aids and services from the 2016 Rule.

Response: The Department’s definition of auxiliary aids and services is consistent with, even if not identical to, that of the ADA. The Department

does not deem it necessary to incorporate all of the ADA’s examples, as neither the ADA’s list nor this final rule’s list claims to be exhaustive.

Comment: Some commenters expressed concern regarding the narrowing of the “free of charge” and “timely manner” provision at proposed § 92.102(b)(2). Commenters noted that the 2016 Rule’s language is consistent with existing ADA Title II regulations, which provide that covered entities may not place a surcharge on a particular individual or group of individuals with a disability to cover the costs of the provision of auxiliary aids or program accessibility. Commenters asserted that the proposed § 92.102(b)(2) significantly narrows this provision by stating that “interpreting service” shall be provided to individuals free of charge and in a timely manner. These commenters strongly opposed this change and encourage the Department to replace the words “interpreting service” with “auxiliary aids and services” to be consistent with the ADA and to prevent unnecessary confusion over the requirement.

Response: Like § 92.202 of the 2016 Rule, which it replaces, § 92.102 of this final rule continues to incorporate the ADA Title II regulations at 28 CFR 35.160–164. The new section also includes new language on the qualifications for interpreters, which is where the term “free of charge” now appears; the term did not appear in § 92.202 of the 2016 Rule. To the extent that auxiliary aids must be provided free of charge under the 2016 Rule, they must still be provided free of charge under this final rule.

Comment: One commenter asked that the phrase “in a timely manner” as used in Section 92.102(b)(2) of the proposed rule be clarified with clear guidance as to what can and cannot be considered “in a timely manner.”

Response: Application of the term “in a timely manner” requires a nuanced analysis that is fact-dependent. Its meaning can be understood from the long history of enforcement of Section 504 and the ADA in the courts and administratively.

Comment: Some commenters supported an exemption from the auxiliary aids and services requirement for covered entities with fewer than 15 employees, stating that it would help alleviate financial and administrative burden for smaller physician group practices that may already have limited resources. Others said that in some areas of the country, especially in small and rural communities, such an exemption could effectively bar access to many providers. Commenters said that any

such exemption would be inconsistent with the standard present in Title II²⁹⁰ and Title III²⁹¹ of the ADA, which require the same businesses to provide auxiliary aids and services to individuals with disabilities where necessary to ensure effective communication, regardless of the number of employees. They said that the existence of two competing regulatory standards will confuse small covered entities as to which standard they should follow. Several commenters noted that although a small economic burden may be placed on small businesses that have to comply with this requirement, there are programs that provide tax benefits and funding for the provision of reasonable accommodations, significantly reducing the burden placed on these entities.²⁹² Some commenters noted that because Titles II and III of the ADA already provide for sufficient mechanisms for providers to request exemptions based on a fundamental alteration in the nature of goods and services provided and undue burden, no additional exemption is needed through Section 1557.

Response: The Department believes that in the interest of uniformity and consistent administration of the law, all employers that receive Federal financial assistance from HHS, regardless of their size, should be held to the auxiliary aids and services requirement. The Department recognizes the importance of individuals being able to effectively communicate with their healthcare providers and is aware that the inability to effectively communicate can have significant adverse effects on individuals’ access to effective healthcare. The Department’s decision to require all entities, regardless of size, to provide auxiliary aids and services is consistent with OCR’s policy for almost two decades,²⁹³ so covered entities will

²⁹⁰ 28 CFR 35.104.

²⁹¹ See 42 U.S.C. 12182(b)(A)(iii) (under Title III, privately operated public accommodations regardless of their size are obligated to provide appropriate auxiliary aids and services, when necessary to ensure effective communication with individuals with disabilities, unless the entity can demonstrate that taking such steps would fundamentally alter the nature of their programs, services or activities, or would result in undue financial and administrative burdens).

²⁹² Commenters cited U.S. Department of Justice American with Disabilities Act Update: A Primer for Small Business. (2010). Retrieved from <https://www.ada.gov/regs2010/smallbusiness/smallbusprimer2010.htm>; Internal Revenue Service. (n.d.); Form 8826, Disabled Access Credit. Retrieved from <https://www.irs.gov/forms-pubs/about-form-8826>.

²⁹³ See Notice of Exercise of Authority Under 45 CFR 84.52(d)(2) Regarding Recipients With Fewer Than Fifteen Employees, 65 FR 79368 (Dec. 19, 2000).

302 F.3d 567, 574 (5th Cir. 2002); *McPherson v. Michigan High School Athletic Ass’n, Inc.*, 119 F.3d 453, 459–60 (6th Cir. 1997); *Gorman v. Bartch*, 152 F.3d 907, 912 (8th Cir. 1998); *Zukle v. Regents of Univ. of Cal.*, 166 F.3d 1041, 1045 n.11 (9th Cir. 1999); *Cohan ex rel. Bass v. N.M. Dept. of Health*, 646 F.3d 717, 725–26 (10th Cir. 2011); *Bircoll v. Miami-Dade Cty.*, 480 F.3d 1072, 1088 n.21 (11th Cir. 2007).

²⁸⁹ 28 CFR 35.104.

be familiar with the obligations being imposed. Title II and Title III of the ADA already require public and private healthcare entities to provide auxiliary aids and services regardless of the number of employees. Both Titles state that an entity is not required to take any action that it can demonstrate would result in a fundamental alteration in the nature of a service, program, or activity or in undue financial and administrative burdens, and § 92.102 incorporates both of those limitations through its incorporation of the ADA Title II regulations at 28 CFR 35.160–164. Therefore, the Department finds it appropriate not to adopt an exemption from the auxiliary aids and services requirement for covered entities with fewer than 15 employees.

Comment: Commenters said that the “primary consideration” standard has evolved such that patients will demand that a particular translator or interpreter be used, regardless of the expense. These commenters argued that when patients demand use of a certain company or specific commercial service, this creates additional unnecessary costs for the covered entity. One commenter stated that Title III of the ADA should be the standard that applies to private businesses covered by Section 1557 regarding effective communication for individuals with disabilities. The commenter asserted that the Title II primary consideration standard is not appropriate for use in a clinical setting and that treating clinicians or the entities themselves are in the best position to determine the types of services necessary to address the communication needs of their patients. The commenter argued that applying Title II standards to private entities has created significant confusion for medical group practices accustomed to following longstanding Title III rules.

Response: Since the 2015 NPRM, the Department has held that it is appropriate, as a condition of receipt of Federal financial assistance from HHS, to hold all recipients to the higher 2010 ADA Title II standards regarding effective communication with individuals with disabilities.²⁹⁴ The Department does not consider the commenters’ concerns to be a sufficient reason to change this policy. Section 92.102 of this final rule seeks to avoid confusion by providing covered entities with clear, specific guidance to help them understand their rights and responsibilities regarding effective communication with individuals with disabilities. As mentioned above, it also

incorporates the “undue burden” and “fundamental alteration” limitations of ADA Title II, in order to avoid excessively burdening covered entities.

(3) Accessibility Standards for Buildings and Facilities (45 CFR 92.103)

The Department proposed at § 92.103(a) to retain the 2016 Rule’s requirement that new construction or alteration of buildings or facilities subject to Section 1557 must comply with the 2010 ADA Standards for Accessible Design by January 18, 2018, and to retain the 2016 Rule’s allowance of departures from the 2010 ADA standards where other methods are permitted that provide substantially equivalent or greater access to and usability of the building. 84 FR at 27867. The Department proposed at § 92.103(b) to create a safe harbor for new construction or alteration of buildings or facilities subject to Section 1557, allowing existing facilities which were only required to be compliant with the Uniform Federal Accessibility Standards (“UFAS”), the 1991 ADA Standards, or the 2010 ADA Standards as of July 18, 2016, to be deemed compliant, unless there is new construction or alteration after January 18, 2018. Finally, the Department proposed at 92.103(c) to identify the three applicable building and facility detailed technical accessibility standards by cross-reference to their underlying regulations, instead of listing them in a separate definitions section.

Upon further consideration of this language and the public comments, the Department observed a potential ambiguity in § 92.203 of the 2016 Rule. The rule distinguished between construction or alteration commenced “on or after July 18, 2016” in the first sentence of § 92.203(a), those commenced “on or before July 18, 2016” in the first sentence of § 92.203(b), and those commenced “before July 18, 2016” in the last sentence of § 92.203(b). This potentially left it unclear how the rule would apply to construction or alteration commenced on July 18, 2016. To avoid confusion, the Department is finalizing § 92.103 with a technical change, by deleting the phrase “on or” from the first sentence of § 92.103(a), and adding “on or” before the word “before” in the last sentence of § 92.103(b). This resolves the ambiguity while providing leeway to activities commenced on July 18, 2016 where it was not clear how the 2016 Rule applied.

Comment: Commenters supported the proposal to continue to apply the 2010 ADA Standards’ definition of “public building or facility” to all entities

covered under Section 1557, by retaining the provisions of 45 CFR 92.203 (redesignated § 92.103) regarding accessibility standards for buildings and facilities. Commenters opposed any type of additional exemption from the requirements concerning multistory building elevators²⁹⁵ and Text Telephone (TTY) requirements.²⁹⁶ Some commenters strongly opposed the proposed rule’s incorporation of the private entity TTY standard from the 2010 ADA Standards, and requested the retention of the existing TTY ratios, and the adoption of stringent Real-Time Text (RTT) ratios. Others noted that lack of accessible medical equipment presents barriers to effective healthcare for people with impaired mobility or strength and other disabilities, and they requested that the Department require healthcare facilities to follow the 2017 Architectural and Transportation Barriers Compliance Board (U.S. Access Board) Standards for Accessible Medical Diagnostic Equipment.²⁹⁷

Response: The Department believes that, because the great majority of entities covered by the 2016 Rule have already been subject to the 2010 ADA Standards, an approach that emphasizes uniform application of the 2010 Standards will promote conformity with pre-existing civil rights statutes while enabling greater consistency among implementing agencies. Any significant reevaluation of those standards or adoption of new standards is beyond the scope of this regulation. In the case of adopting new standards, the Department also declines to make such a significant regulatory change without the benefit of notice and public comment.

(4) Accessibility of Information and Communication Technology (45 CFR 92.104)

The Department proposed to retain the 2016 Rule’s provisions on accessibility of information and communication technology for individuals with disabilities. 84 FR at 27867. The Department also proposed at 92.104(c) to update the 2016 Rule’s

²⁹⁵ See 42 U.S.C. 12101 *et seq.* Exception 1 of section 206.2.3 of the 2010 ADA standards exempts multistory buildings besides the professional office of a healthcare provider owned by private entities from the requirement to provide an elevator to facilitate an accessible route throughout the building. This exemption does not apply to public entities.

²⁹⁶ The 2010 ADA Standards also specifies TTY requirements for public buildings different from private buildings. Compare ADA 2010 Standard 217.4.3.1 (public buildings) with ADA 2010 Standard 217.4.3.2 (private buildings).

²⁹⁷ See Information and Communication Technology (ICT) Standards and Guidelines, 82 FR 5790 (Jan. 18, 2017) (final rule); 83 FR 2912 (Jan. 22, 2018) (technical edits).

²⁹⁴ 80 FR 54186.

outdated term “electronic and information technology” with the term “information and communication technology,” as defined in the U.S. Access Board regulations. 84 FR at 27871.

Comment: Commenters expressed concern with the Department’s proposed change to the definition of “information and communication technology” (ICT), in proposed § 92.104(c). Commenters noted that the critical phrase “but are not limited to” has been removed from the definition the Department claims to have incorporated from the U.S. Access Board’s definition for ICT.²⁹⁸ The commenters argue that due to the difficulty in predicting what technologies will be in place moving forward, it is important to maintain flexibility and ensure that the regulation keep pace with emerging technologies.

Response: The list of auxiliary aids was not intended as an all-inclusive or exhaustive catalogue of possible or available auxiliary aids or services—nor could it possibly be, given the new devices that will become available with emerging technology. The Department omitted the phrase “but are not limited to” merely in order to avoid unnecessary legal jargon. The plain meaning of “include” already encompasses “but are not limited to,” as it signifies that the listed items are only parts of a larger whole.

Comment: One commenter requested that the Department require recipients of Federal financial assistance to ensure that health programs or activities provided through their websites comply with the requirements of Title III, rather than Title II, of the ADA, if the recipient is otherwise covered by Title III. The commenter argued that the burden placed on small practices by having to comply with both Title II and Title III would likely outweigh any benefit to individuals who require accessible technology.

Response: The Department believes that this comment understates the benefit of the Title II standards to individuals who require accessible technology. Effective communication is a critical component for individuals to

be able to access and receive healthcare, and this includes being able to access covered entities’ websites. The Department believes that in the interest of uniformity of access for individuals with disabilities, all entities that receive Federal financial assistance from HHS should be held to the higher information and communication technology standards of Title II. The ADA does not exempt small providers from this requirement, although § 92.104 does incorporate the ADA’s “undue financial and administrative burden” and “fundamental alteration” exemptions in order to protect covered entities from excessive burdens.

Comment: Some commenters stated that the Department should cross-reference Section 508 in its proposed § 92.104. The commenters noted that although the proposed rule tracks the concepts of the Section 508 regulations, it does not include the appropriate cross-reference, which will cause confusion if and when the Section 508 regulations are updated.

Response: If and when Section 508 regulations are updated, the Department will evaluate whether or not to update § 92.104 accordingly. Because this final rule does not incorporate Section 508 regulations but merely tracks them, the Department believes that a cross reference could cause unnecessary confusion if and when Section 508 regulations are updated or changed.

(5) Requirement To Make Reasonable Modifications (45 CFR 92.105)

The Department proposed at § 92.105 to retain the 2016 Rule’s requirement that covered entities make reasonable modifications to policies, practices, or procedures when necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that the modification would fundamentally alter the health program or activity. 84 FR at 27868. The Department sought comment on whether to include an exemption for “undue hardship.” *Id.*

Comment: Commenters strongly opposed an exemption for undue hardship in regard to the requirement that covered entities make reasonable modifications to policies, practices, or procedures when necessary, to avoid discrimination on the basis of disability, except if the modification would fundamentally alter the nature of the health program or activity. Commenters pointed out that the current regulations track Title II of the ADA. Commenters stated that Title III does not absolve a covered entity from providing all forms of auxiliary aids if providing a particular auxiliary aid would result in

undue burden, and that a provider has an obligation to find an alternative auxiliary aid in such cases. Commenters noted that because Title II and III of the ADA already provide mechanisms for providers to request exemptions based on an undue burden, no additional exemption is needed. Commenters stated that the substitute language proposed is from regulations related to employment and ill-fitting and inappropriate in a healthcare context. Commenters requested that if an exemption for undue hardship is provided, it should mirror the undue burden provision of the ADA, to ensure the two Federal laws are in sync and do not conflict with one another and lead to confusion.

Response: The Department agrees with commenters who ask that the regulations continue tracking Title II of the ADA, whose requirement for reasonable modifications includes a fundamental alteration exemption but no undue hardship exemption. The Department believes that this position helps promote continued consistency with pre-existing civil rights statutes. The reasonable modification analysis already applies to many entities subject to Section 1557 and is well-defined by regulation and decades of case law. Continuing to apply the “reasonable modification” analysis to Section 1557 promotes consistency with pre-existing civil rights law and is consistent with the U.S. Supreme Court’s decision interpreting Section 504 in *Alexander v. Choate*, 469 U.S. 287 (1985), Title II of the ADA, and OCR’s longstanding interpretation of Section 504.

Comment: Commenters objected to substituting the Title II reasonable modification language with language stating that covered entities “shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified” individual with a disability. Further, a commenter argued that use of the term “known,” outside the employment context, would suggest an overly narrow interpretation of the scope of Section 1557 and introduce an unnecessarily burdensome and intrusive process into the healthcare context. Commenters expressed concern that importing the “known physical or mental limitation” language would suggest to covered entities that their obligations are limited, and would create an undue focus on the measures that entities must take in response to requests for modifications.

Response: The Department shares the concern that introduction of the phrase “known physical or mental limitations” may cause covered entities to introduce

²⁹⁸ See 36 CFR app. A § 1194 (2011) (defining ICT as “Information technology and other equipment, systems, technologies, or processes, for which the principal function is the creation, manipulation, storage, display, receipt, or transmission of electronic data and information, as well as any associated content. Examples of ICT include but are not limited to: Computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; customer premises equipment; multifunction office machines; software; applications; websites; videos; and electronic documents.”).

exceedingly burdensome and intrusive processes into the healthcare context. In contrast, the concept of reasonable modification taken from Title II has long applied to a wide range of entities covered by Section 1557, making such entities familiar with the requirements imposed, and is well-defined by regulation and decades of case law. The Department believes that continuing to apply the reasonable modification analysis to Section 1557 will help promote consistency with pre-existing civil rights statutes.

Comment: Several commenters noted that the citation for the proposed reasonable modification language the Department claims conforms to the Department of Justice's Section 504 coordinating regulations is to a non-existent portion of the Code of Federal Regulations. These commenters argue that these incorrect citations make it impossible for the public to analyze the context or case law of the proposed imported language and that such uncertainty makes it impossible for the public to reliably know what the Department is proposing.

Response: The Department thanks these commenters for bringing this citing error to its attention. For clarity, the Department notes that it intended to cite to 28 CFR 42.511, not § 92.205.²⁹⁹ But for the reasons stated above, the Department has determined that it should retain the current Title II reasonable modification language.

Comment: Some commenters recommended that the rule include the addition of examples of programmatic modifications that are often needed by those with disabilities, such as the modification of wait times, office hours, and other business practices that can make accessibility to healthcare for people with disabilities difficult.

Response: The Department declines to enshrine a list of examples of "programmatic modifications" needed by those with disabilities. Because this final rule applies to a diverse range of covered entities, codifying examples would not provide meaningful guidance to the full spectrum of regulated covered entities. The Department believes that each covered entity ought to determine for itself which programmatic modifications with respect to its health programs and activities should be undertaken to avoid discrimination on the basis of disability, subject to enforcement by OCR in case of a complaint.

Comment: Commenters found inappropriate the Department's requesting comment on whether it has

struck the appropriate balance in proposed §§ 92.102 through 92.105 with respect to Section 504 rights and obligations imposed on the regulated community, as such a balancing exercise is not called for by the statute and inserts inappropriate regulatory subtlety.

Response: In any rulemaking, addressing obstacles that impede individuals from exercising their rights should be balanced against potentially unnecessary obligations that may be imposed on the regulated community. Agencies engage in this type of balancing in order to ensure that the interests and issues of both individuals and the regulated community are fairly considered during the rulemaking process, helping to minimize the burden associated with Federal regulations.

Comment: A commenter said that in order to promote clarity and affirm that VRI quality standards apply in any remote interpreting situation that may arise for a person with a disability, § 92.101 of the proposed rule ought to cross-reference the VRI quality standards in § 92.102.

Response: Section 92.102 covers individuals with disabilities. § 92.101 covers individuals with LEP status, which is not a disability. Individuals with disabilities have different needs than LEP individuals, and the current regulatory text reflects that difference. If an LEP individual happens also to have a disability, then the VRI quality standards of § 92.102 will apply to him/her.

(6) Summary of Regulatory Changes

The Department finalizes the proposed sections § 92.101 through 92.105 without change, except that technical changes are made to add the word "or" at the end of § 92.101(b)(4)(ii)(A), to delete the phrase "on or" from the first sentence of § 92.103(a), and to add the phrase "on or" before the word "before" in the last sentence of § 92.103(b).

D. Title IX Regulations

The Department proposed to conform its Title IX regulations to current statutory provisions.

(1) Nomenclature, Rules of Appearance, Effective Date Modifications to Rules at 45 CFR 86.31 and 86.71

The Department proposed to make a nomenclature change to the Title IX regulation by replacing "United States Commissioner of Education" with the official's current title, "Secretary of Education."³⁰⁰ The Department also

proposed to update the Title IX regulation's statutory citations to include the full current text of Title IX as amended by the CRRRA.

The Department also proposed to repeal a prohibition on discrimination on the basis of "rules of appearance" in 45 CFR 86.31. The Department further proposed to update the enforcement section in the Department's Title IX regulation at 45 CFR 86.71, which currently discusses only enforcement procedures for the interim period before the issuance of the consolidated Title IX regulation. This final rule applies language from the Title IX regulation, which incorporates Title VI procedures.

Comment: The Department received comments indicating that the rules of appearance prohibition is well supported by Title IX and that HHS provides no basis for removing the prohibition.

Response: This final rule's NPRM explained that currently, the Department is the only Federal agency with Title IX regulatory language prohibiting discrimination "against any person in the application of any rules of appearance."³⁰¹ The phrase "rules of appearance" does not appear in Title IX and was never defined in any agency's Title IX regulations. Consequently, the Department believes the phrase may cause confusion in the public about Title IX's coverage and compliance responsibilities, and has already led to at least one lawsuit. Because this language is not in the current regulations of any other agencies, this final rule limits the potential for conflicting and inequitable Federal agency enforcement of Title IX with respect to "rules of appearance."

(2) Abortion Neutrality of 20 U.S.C. 1688 in 45 CFR 86.2 and 86.18

The Department also proposed to modify its Title IX regulations, at 45 CFR 86.18, to reflect the statutory text Congress enacted in Title IX. This text includes what some commenters referred to as the Danforth Amendment, 20 U.S.C. 1688, which states that Title IX is not to be construed to force or require any individual or hospital or any other institution, program, or activity receiving Federal funds to perform or pay for an abortion; to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use

²⁹⁹ See 84 FR 27868 (citing to 28 CFR 92.205).

³⁰⁰ See 45 CFR 86.2(n).

³⁰¹ See, e.g., 47 FR 32527 (July 28, 1982) (Department of Education Title IX regulation); 65 FR 52858 (Aug. 30, 2000) (common rule adopted by twenty agencies); 66 FR 4627 (Feb. 20, 2001) (common rule adopted by Department of Energy); 82 FR 46656 (Oct. 6, 2017) (U.S. Department of Agriculture adopting common rule).

of facilities, related to an abortion; or to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion.³⁰² The Department also proposed to add a provision, similar to the provision of the Section 1557 regulation discussed above under “relation to other laws,” ensuring that its Title IX regulation would be construed consistently with various religious freedom and conscience statutes, including the explicit religious exemptions in the text of Title IX itself.

Comment: One commenter stated that adding Title IX’s abortion neutrality language in the Department’s Title IX regulations would be a violation of the plain language of the definition of sex discrimination in the regulations, which includes termination of pregnancy. Others noted that discrimination based on termination of pregnancy has been recognized by courts as sex discrimination and therefore argued that the proposed rule is contrary to civil rights laws and constitutional principles. Some noted that Title IX itself expressly does not permit penalties based on a woman’s prior termination of pregnancy.

Others, however, supported the incorporation of Title IX’s religious exemptions and other Federal conscience statutory protections, arguing that they are consistent with abortion neutrality. Still others stated that discrimination on the basis of sex should not include termination of pregnancy at all, under existing law and the statutory text of Section 1557 and Title IX. Some submitted legislative history from Title IX (Senate Committee Report 100–64) to show that Congress intended to allow for abortion exemptions and exclusion of health insurance coverage for abortion services, and that Congress did not intend to require all hospitals to provide abortion services to the general public.³⁰³ But other commenters were critical of using legislative history to interpret a statute.

³⁰² See Public Law 100–259, 102 Stat. 28, sec. 8 (Mar. 22, 1988) (codified at 20 U.S.C. 1688).

³⁰³ See Senate Committee Report 100–64 (“This bill does not expand abortion rights. Religiously-controlled organizations will continue to be able to apply for, and receive, an exemption from Title IX requirements where compliance with those requirements would violate their religious tenets. For example, a religiously controlled university that wished to exclude insurance coverage of abortions from an otherwise comprehensive student health insurance policy, could seek a religious exemption. . . . Title IX covers only students and employees, and does not reach the public at large. Therefore, claims that the bill would require hospitals to provide abortion services to the general public are false.”).

Response: This final rule does not remove the language from the Department’s Title IX regulations that prohibits certain forms of discrimination on the basis of “termination of pregnancy.”³⁰⁴ However, as stated above in the section on discrimination on the basis of sex (subsection on “termination of pregnancy”), the Title IX regulations are governed by the text of the Title IX statute and cannot be “construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion” (20 U.S.C. 1688). This final rule adds language to the Title IX regulations in order to make this clear. Although some commenters cite legislative history, the Department interprets the statutory text as written. Regardless, the Department does not believe there is tension between the legislative history and the text.

By adding the abortion neutrality language to the Title IX regulations, and stating in the Section 1557 regulation that it will be applied consistent with Title IX (including that language), this final rule ensures compliance with the rationale in *Franciscan Alliance*, where the Court rightly held that the Department’s regulations forbidding discrimination on the basis of sex must be construed in light of the underlying text of Title IX, including abortion neutrality.

Comment: Commenters stated that religious exemptions would make it harder to find healthcare in low provider areas, and that religious refusals also harm people who live in rural areas and must travel for an abortion. However, other commenters stated that this inclusion of various Federal conscience statutes and appropriations riders would ensure that healthcare providers who have conscience objections to abortion will feel welcome within the healthcare profession and will ease retention of healthcare providers already in the field.

Some specifically stated their support for the Department’s inclusion of the First Amendment, and for Department guidance that the proposed rule be construed consistent with religious liberty and free speech protections, to clarify that the interpretation, application, and enforcement of the proposed rule will be consistent with religious liberty. Other commenters stated that referring to the First

³⁰⁴ See 45 CFR § 86.21(c)(3), 86.40(b)(1), 86.40(b)(4), 86.40(b)(5), 86.51(b)(2), 86.51(b)(6), 86.57(b), 86.57(c), 86.57(d).

Amendment rightly addresses the recent Supreme Court ruling in *NIFLA v. Becerra*.³⁰⁵ Commenters were concerned that the 2016 Rule would require a faith-based hospital to inform a patient about terminating her pregnancy in direct contravention of sincerely-held religious beliefs. This would be in conflict with *NIFLA*, where the Supreme Court held that such a mandate “imposes an unduly burdensome disclosure requirement that will chill [] protected speech.”³⁰⁶

Response: The Department agrees that this final rule should be construed consistent with the First Amendment, conscience statutes, and all relevant statutes and appropriations riders relating to abortion, to the extent they remain in effect or applicable. Agency regulations are subject to the requirements of the First Amendment in any case, and the Department considers it appropriate to say so explicitly here. All the other laws referenced establish Congressionally required parameters that may apply to the Department’s interpretation, implementation, and enforcement of Title IX and of this final rule.³⁰⁷ Commenters’ policy objections to these statutory constraints are not a sufficient reason for the Department not to finalize this provision of the rule, which will ensure compliance with statutory requirements.

(3) Summary of Regulatory Changes

For the reasons described herein and having considered the comments received, the Department finalizes changes to 45 CFR 86.2, 86.18, 86.31, and 86.71 without change.

E. Conforming Amendments to CMS Regulations

The Department proposed to make conforming amendments to ten regulations of CMS that prohibited discrimination on the basis of gender identity and/or sexual orientation in the establishment and operation of ACA exchanges; in the marketing and design practices of health insurance issuers under the ACA; in the administration, marketing, and enrollment practices of QHPs under the ACA; in beneficiary enrollment and the promotion and delivery of services under Medicaid; and in the delivery of services under the PACE program. These conforming changes were proposed, among other

³⁰⁵ *Natl. Inst. of Fam. and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018).

³⁰⁶ *Id.* at 2378.

³⁰⁷ To the extent the relevant provisions are found in an appropriations rider, they apply to the Department’s interpretation, implementation, and enforcement of Title IX every year that they are enacted.

reasons, to ensure uniformity across the Department with respect to regulations that cover many of the same entities.

(1) Generally

Comment: Several commenters contended that the proposed rule exceeds the authority of the Director of OCR by attempting to remove references to gender identity and sexual orientation from all HHS healthcare regulations, including those issued by other HHS agencies unrelated to Section 1557, although the rule purported to be promulgated by authority from Section 1557 and other sections within the ACA. Commenters stated that the nondiscrimination protections proposed to be eliminated from CMS regulations are unrelated to Section 1557 and its regulation, and that this elimination was proposed without sufficient legal, policy, or cost-benefit analyses as well as without knowledge of their potential impacts on various CMS programs and on LGBT patients, who (commenters said) may be discriminated against if these amendments are finalized. Also, commenters contend the conforming amendments, if implemented, would affect a wide range of healthcare programs, including private insurance and education programs. Some said they were unaware of any instances in which inclusion of sexual orientation as a basis for nondiscrimination in these CMS rules had been challenged or opposed. Others said that it was arbitrary to single out sexual orientation and gender identity for elimination, since some of the CMS regulations being amended also protect other characteristics not expressly enumerated by statute.

Response: Both the proposed rule and this final rule are promulgated by the Secretary of Health and Human Services, who has jurisdiction over all Department regulations, including those falling under the jurisdiction of CMS. Moreover, each of the programs, activities, or entities in the proposed conforming amendments falls within the scope of Section 1557 as entities established under Title I of the ACA (for example, Exchanges³⁰⁸), entities administered under Title I of the ACA (for example, QHPs³⁰⁹) or health programs or activities receiving Federal financial assistance from the Department, including contracts of insurance.³¹⁰ The ACA and certain

Federal statutes identifying other protected categories provide the bases for the nondiscrimination clauses in health programs and activities funded or administered by HHS.³¹¹

The Department has reviewed the legal authorities underlying and cited in the nondiscrimination provisions of these CMS regulations and the explanations set forth in those rules. Some of them relied on or referenced Section 1557, some relied on different statutory provisions, and some are cross-referenced in the 2016 Rule. None of the statutory authorities underlying the CMS rules amended here explicitly references sexual orientation or gender identity. To the extent some of those regulations were promulgated based on broad authority to issue regulations,³¹² inclusion of nondiscrimination criteria that are not explicitly set forth in other applicable civil rights statutes may not necessarily exceed the Department's statutory authority. Nevertheless, the Department deems it appropriate to pursue a more uniform practice concerning nondiscrimination categories across programs and activities to which Section 1557 applies, and to do so consistent with the government's position concerning discrimination on the basis of sex.

In addition, for several of the CMS final rules, their corresponding proposed rules had not mentioned adding sexual orientation and gender identity as nondiscrimination categories.³¹³ Although some of those proposed rules also did not mention adding other common nondiscrimination categories, the Department now views the addition of sexual orientation and gender identity as nondiscrimination categories as having presented different legal and policy concerns from other categories. Notably, these nondiscrimination categories are not required by applicable law, appear in only a handful of federal antidiscrimination statutes, and have

Prepaid Inpatient Health Plans, (PIHPs), Medicaid Prepaid Ambulatory Health Plans (PAHPs), Medicaid Primary Care Case Managers (PCCMs), Primary Care Case Management Entities (PCCM-Es) and Programs for All-inclusive Care for the Elderly serving Medicare and Medicaid beneficiaries (PACE).

³¹¹ See 42 CFR 438.3(d)(4), 438.206(c)(2), 440.262, 460.98(a)(3), 460.112(a).

³¹² See, e.g., ACA Section 1321 (42 U.S.C. 18041(a)) (authorizing the Secretary to "issue regulations setting standards . . . with respect to . . . the establishment and operation of Exchanges . . . the offering of qualified health plans through such Exchanges . . . and . . . such other requirements as the Secretary determines appropriate").

³¹³ See, e.g., 78 FR 13406 (Feb. 27, 2013) (final rule) and 77 FR 70584, 70585 (Nov. 26, 2012) (NPRM).

been the subject of extensive litigation, controversy, and confusion generally. Thus, the Department believes the addition of sexual orientation and gender identity as nondiscrimination categories in its regulations should have been submitted for public comment and, notwithstanding the lack of legal challenge to these CMS regulations on this basis, proposes conforming amendments for purposes of clarity, consistency, and uniformity.

Therefore, the Department deems it appropriate to finalize the proposed conforming amendments to these CMS regulations without change (with the exception of a technical correction described below), in order to create a more uniform practice concerning nondiscrimination on the basis of sex among HHS programs to which Section 1557 applies, and to avoid the possibility that there was insufficient statutory authority to impose gender identity or sexual orientation nondiscrimination prohibitions through those regulations.

The Department is unaware of any data that would make cost-benefit analyses for these specific changes possible, and notes that the insertion of sexual orientation and gender identity language (repealed by these amendments) had already been implemented without any cost-benefit analyses. These provisions are eliminated for reasons parallel to those put forth here and in the proposed rule with respect to proper statutory construction, legal authority, and the Department's policy goals.

Comment: Some commenters supported proposals to remove the provisions prohibiting discrimination on the basis of sexual orientation specifically from regulations encompassed by the conforming amendments, in order to reflect current law and current regulatory policy. They reiterated the 2016 Rule's statement that there is no settled statutory law or court-settled law that discrimination on the basis of sexual orientation is legally included within the reach of Title IX.

Response: For the reasons explained above, the Department agrees with the 2016 Rule's decision not to include an explicit prohibition on sexual orientation discrimination. Similarly, the Department concludes it is appropriate to remove such language through these conforming amendments.

(2) Delivery of Medicaid Services (42 CFR 438.3(d)(4), 438.206(c)(2), 440.262)

The Department proposed conforming amendments to multiple provisions in Title 42 of the Code of Federal Regulations that apply to delivery of

³⁰⁸ See Public Law 111–148, tit. I, subtit. D, Part II (Consumer Choices and Insurance Competition Through Health Benefit Exchanges).

³⁰⁹ See Public Law 111–148, tit. I, subtit. D, Part I (Establishment of Qualified Health Plans).

³¹⁰ These include Medicare Advantage (Medicare Part C) plans, Medicare Part D plans, Medicaid Managed Care Organizations (MCOs), Medicaid

Medicaid services found in § 438.3(d)(4) as applied to MCOs, PIHPs, PAHPs, PCCMs or PCCM entities, § 438.206(c)(2) by MCOs, PIHPs, and PAHPs participating in State efforts, and § 440.262 by the States themselves.

Three of the provisions applied to Medicaid managed care. The Department proposed on June 1, 2015, and then finalized on May 6, 2016, a regulation with several nondiscrimination provisions applicable to fee-for-service medical assistance under Medicaid. 80 FR 31098 (June 1, 2015) (Medicaid NPRM); 81 FR 27895 (May 6, 2016) (Medicaid final rule). The Department prohibited discrimination on the basis of “sexual orientation and “gender identity” by MCOs, PIHPs, PAHPs, PCCMs, and PCCM-Es. 42 CFR 438.3(d)(4). And it required that certain of these entities promote access and/or delivery of services “in a culturally competent manner to all enrollees . . . regardless of gender, sexual orientation or gender identity.” 42 CFR § 438.206(c)(2).

In promulgating these regulations, the Department relied on a statute granting general rulemaking authority to the Secretary of HHS to make and publish rules and regulations as may be necessary to efficiently administer Medicare and Medicaid. Section 1102 of the Social Security Act, 42 U.S.C. 1302(a). It also cited provisions of the Social Security Act that require Medicaid State plans for medical assistance to “provide . . . such methods of administration . . . as are found by the Secretary to be necessary for the proper and efficient operation of the plan.” Section 1902(a)(4) of the Social Security Act (42 U.S.C. 1396a(a)). And it cited Section 1902(a)(19) of the Social Security Act to justify additional methods of administration and new protected categories necessary for the proper operation of a State plan, for best interest of the beneficiaries, and for cultural competency. 81 FR 27895 (Medicaid final rule). None of these authorities prohibits discrimination on the basis of gender identity or sexual orientation.

In reviewing § 440.262, the Department became aware that in proposing a conforming amendment to the first sentence, the proposed rule is worded to delete the second sentence of that section, which reads “These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meets their unique needs.” The Department’s intent was to make a conforming amendment to the first sentence of that section, but not to delete the second sentence. Therefore, the Department finalizes the

conforming amendment to the first sentence of § 440.262 without change, but makes a technical correction by finalizing the section to retain the second sentence of that section. In other words, the Department is finalizing the change to the first sentence of § 440.262, but is not finalizing the deletion of the second sentence. In addition, the Department corrects the grammar of the second sentence, by changing the word “meet” to “meets.” Medicare’s PACE Program Employees and Organizations (42 CFR 460.98(b)(3), 460.112(a)).

The Department proposed conforming amendments to two provisions that apply to PACE, a health program receiving HHS Federal financial assistance that is therefore subject to Section 1557.

In 2006, the Department promulgated a regulation administering PACE that prohibited discrimination on the basis of sexual orientation. 71 FR 71244 (Dec. 8, 2006) (PACE final rule). Sexual orientation had not been identified as a protected category in the statute authorizing PACE. *See* Public Law 98–21, as amended (codified at 42 U.S.C. 1396u–4 *et seq.*).

In the PACE final rule, in response to a request from two commenters to “broaden the list of categories under which the PACE Organization cannot discriminate to include sexual orientation,” the Department agreed to amend 42 CFR 460.98(b)(3) to prohibit discrimination on the basis of sexual orientation for Medicare and Medicaid participants. The PACE proposed rule also prohibited discrimination on the basis of sexual orientation by employees and contractors of Medicare-participating PACE programs. 42 CFR 460.112(a) (providing that “[e]ach participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment”).

Medicare Part A programs, including PACE, are subject to Title VI, Title IX, Section 504, and the Age Act. OCR has the authority to review recipient policies and procedures and certify that recipients of Federal financial assistance under Medicaid Part A comply with Title VI, Title IX, Section 504, and the Age Act, and their implementing regulations. CMS now directs applicants to an online attestation portal on the OCR website to assure compliance with those four civil rights statutes as well as with Section 1557.

In reviewing § 460.112(a), the Department became aware that in proposing a conforming amendment to

the first two sentences, the proposed rule is worded to delete the remainder of the subsection. The Department’s intent was to make a conforming amendment to the first two sentences of subsection (a), but not to delete its remainder. Therefore, the Department finalizes the conforming amendment to the first two sentences of § 460.112(a) without change, but as a matter of technical correction does not finalize the deletion of the remaining sentences, and instead finalizes subsection (a) to retain the remainder of that subsection.

Comment: Commenters expressed concern that PACE organizations would be allowed to discriminate against LGBTQ people under the proposed rule.

Response: The Department believes that everyone should be treated with dignity and respect and given every protection afforded by the Constitution and the laws passed by Congress. None of the statutes authorizing the PACE regulations prohibits discrimination on the basis of gender identity or sexual orientation.

(3) General Standards for Exchanges, QHPs for Exchanges, and Health Plan Issuers (45 CFR 155.120(c)(ii), 156.200(e))

In 2012, the Department added “sexual orientation” and “gender identity” into certain regulations for the administration of the ACA by States, the Exchanges, and QHP issuers. 77 FR 18469 (Mar. 27, 2012) (“Administration of Exchanges final rule”). The Department cited Section 1321 of the ACA as its authority to add new nondiscrimination requirements. 76 FR at 41873, 41897 (July 15, 2011) (“Administration of Exchanges proposed rule”).

Section 1321 is a general regulatory provision allowing HHS to regulate establishment, operation, and standards in Exchanges and for QHPs. It does not contain the words “sexual orientation” or “gender identity,” or specify that the authority to set standards includes the authority to specify classes protected from discriminatory conduct that are not otherwise specified in nondiscrimination statutes.³¹⁴ Sections 155.120(c)(ii) and 156.200(e) were both later referenced in the preamble to the 2016 Rule as nondiscrimination provisions that the 2016 Rule

³¹⁴ Section 1321(a) of the ACA provides that the Secretary of the Department of Health and Human Services “shall, as soon as practicable after the date of enactment of this Act, issue regulations setting standards for meeting the requirements under this title, and the amendments made by this title, with respect to—(A) the establishment and operation of Exchanges (including SHOP Exchanges); (B) the offering of qualified health plans through such Exchanges . . .” 42 U.S.C. 18041(a)(1)(A)–(B).

“complements.” See 81 FR 31376, 31428 (May 18, 2016). The 2016 Rule also provided that the States, Exchanges, and issuers are “obligated to comply with both sets of requirements.” *Id.*

(4) Guaranteed Coverage (45 CFR 147.104(e))

In the February 27, 2013 edition of the **Federal Register**, the Department finalized a new regulation expanding the nondiscrimination provisions applicable to QHP issuers, including prohibitions on discrimination on the basis of gender identity and sexual orientation, citing Section 1321(a) of the ACA as the applicable statutory authority. 78 FR 13406 (Guaranteed Coverage final rule, codified at 45 CFR 147.104(e)). Nevertheless, the language in the final rule prohibiting discrimination on the basis of gender identity and sexual orientation was not in the proposed rule. See 77 FR 70584, 70613 (Nov. 26, 2012). It appears that the Department added this language in response to a commenter asking that HHS “broaden[] [§ 147.104(e)] to apply to all forms of discrimination prohibited by the March 27, 2012 Exchange final rule and section 1557 of the Affordable Care Act, such as discrimination based on age, disability, race, ethnicity, gender, and sexual orientation, not just discrimination against individuals with significant or high cost healthcare needs.” 78 FR at 13417.

As legal authority, the Department also relied on Section 2702 of the Public Health Service Act, as amended by the Affordable Care Act, Public Law 111–148 (Mar. 23, 2010), which only required that any “individual or group market in a State must accept every employer and individual in the State that applies for such coverage.” There was no explicit reference to categories of individuals protected by nondiscrimination laws.

The rule administered the ACA’s guarantee of coverage in the group and individual health insurance markets. See 42 U.S.C. 300gg–1. The Department attached the sexual orientation and gender identity nondiscrimination provision as part of the requirement for issuers to accept every employer and individual in the State who applies for coverage, subject to a few exceptions. Section 300gg–1 does not specify nondiscrimination criteria, including sexual orientation or gender identity.

The rule applied not only to the health plan issuer but also to its “officials, employees, agents and representatives.” 45 CFR 147.104(e). It prohibited these covered entities from discriminating based on a variety of

bases, including an individual’s sex, sexual orientation, or gender identity. *Id.* In the Guaranteed Coverage final rule, the Department justified the 45 CFR 147.104(e) nondiscrimination provision on the ground that it “ensures consistency with . . . the non-discrimination standards applicable to QHPs under § 156.200(e),” to which sexual orientation and gender identity provisions had previously been added (as described above). 78 FR at 13426. The Guaranteed Coverage final rule was also referenced in the preamble to the 2016 Rule, which described it as both “independent of” and “complement[ary]” to Section 1557. 81 FR at 31428.³¹⁵

The Department notes that this amendment to the Guaranteed Coverage final rule does not negate the rule’s requirement that health insurance issuers offering group or individual coverage “must offer to any individual or employer in the State all products that are approved for sale in the applicable market, and must accept any individual or employer that applies for any of those products.” 45 CFR 147.104(a). That requirement applies independent of the explicit nondiscrimination categories set forth in § 147.104(a).

(5) Enrollment in QHPs Through Exchanges by Agents or Brokers (45 CFR 155.220(j)(2)(i))

In the December 2, 2015 edition of the **Federal Register**, the Department proposed a rule that would prohibit agents or brokers from discriminating on the basis of sexual orientation and gender identity when assisting individuals and employers in applying for or enrolling in QHPs sold through a Federally-facilitated Exchange. 80 FR 75488. This proposed rule was adopted without change in March of the following year. 81 FR 12204 (Mar. 8, 2016) (codified at 45 CFR 155.220(j)(2)(i)). The final rule also stated that covered entities must comply with “certain other Federal civil rights laws [that] impose non-discrimination requirements,” such as Section 1557 of the ACA.³¹⁶ The final rule further

³¹⁵ See 81 FR 31376, 31428 (May 18, 2016) (“We noted that this section [92.207] is independent of, but complements, the nondiscrimination provisions that apply to . . . issuers of qualified health plans under other Departmental regulations, and that entities covered under those provisions and Section 1557 are obligated to comply with both sets of requirements.”).

³¹⁶ 81 FR 12312 (“Issuers that receive Federal financial assistance, including in connection with offering a QHP on an Exchange, are subject to Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, and section 1557 of the Affordable Care Act”).

directed issuers who seek certification of one or more QHPs to the OCR website for information about the Section 1557 NPRM.³¹⁷

(6) Enrollment in QHPs and Exchanges by QHP Issuers (45 CFR 156.1230(b)(2))

In the September 6, 2016 edition of the **Federal Register**, the Department proposed a gender identity and sexual orientation nondiscrimination provision to rules governing marketing or conduct by issuers of individual market QHPs sold through the Federally-facilitated Exchanges in the direct enrollment of individuals in a manner that is considered to be through the Exchange. 81 FR 61456. The rule proposed that QHP issuers would be required to “refrain from marketing or conduct that is misleading . . . coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.” *Id.* The proposed language was finalized that December. 81 FR 94058 (Dec. 22, 2016) (codified at 45 CFR 156.1230(b)(3), since redesignated as 45 CFR 156.1230(b)(2) (see 84 FR 17454, 17568 (Apr. 25, 2019, effective June 24, 2019))). The Department cited Section 1321 of the ACA as its authority to promulgate the nondiscrimination provision. The authority section of the regulation also encompasses Section 1311 of the ACA, which prohibits QHPs from “employ[ing] marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs.”³¹⁸

(7) Summary of Regulatory Changes

The Department finalizes without change the proposed conforming amendments at 42 CFR 438.3(d), 438.206(c)(2), and 460.98(b)(3), and 45 CFR§ 147.104(e), 155.120(c)(ii), 155.220(j)(2)(i), and 156.200(e). It finalizes the proposed conforming amendment of the first sentence of § 440.262 without change, but retains the second sentence of that section without deleting it, and makes one grammatical correction to the second sentence. It finalizes the proposed conforming amendment of the first two sentences of § 460.112(a) without change, but retains the remainder of that subsection without deleting it.

With respect to 45 CFR 156.1230(b)(2), the proposed rule indicated it would amend § 156.1230(b)(3), but effective June 24, 2019, § 156.1230(b)(3) was redesignated as § 156.1230(b)(2). See 84 FR at 17568.

³¹⁷ *Id.*

³¹⁸ 42 U.S.C. 18031.

Therefore, this rule finalizes the change at the redesignated location of the text at § 156.1230(b)(2).

IV. Regulatory Impact Analysis

The Department has examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993); Executive Order 13563 on Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011); Executive Order 13132 on Federalism, 64 FR 43255 (Aug. 4, 1999); Executive Order 13175 on Tribal Consultation, 65 FR 67249 (Nov. 6, 2000); Executive Order 13771 on Reducing Regulation and Controlling Costs, 82 FR 9339 (Jan. 30, 2017); the Congressional Review Act (Pub. L. 104–121, sec. 251, 110 Stat. 847 (Mar. 29, 1996)); the Unfunded Mandates Reform Act of 1995, Public Law 104–4, 109 Stat. 48 (Mar. 22, 1995); the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164 (Sept. 19, 1980); Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking, 67 FR 53461 (Aug. 16, 2002); Executive Order 12250, Leadership and Coordination of Nondiscrimination Laws, 45 FR 72995 (Nov. 2, 1980), and the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*

A. Executive Orders 12866 and Related Executive Orders on Regulatory Review

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to Executive Order 12866 and reaffirms the principles, structures, and definitions governing regulatory review established there.

As discussed below, the Department has estimated that this final rule will have a beneficial effect on the economy greater than \$100 million in at least one year. Thus, it has been concluded that this final rule is economically significant. It has, therefore, been determined that this final rule is a “significant regulatory action” under Executive Order 12866 and, accordingly, the Office of Management and Budget (OMB) has reviewed this final rule.

The executive summary at the beginning of this preamble contains a summary of this final rule in its summary of major provisions, and describes the reasons it is needed in describing the purpose of this final rule.

(1) Consideration of Regulatory Alternatives

The Department carefully considered several alternatives, including the option of not pursuing any regulatory changes, but rejected that approach for several reasons.

First, not pursuing any regulatory changes would be inconsistent with the Administration’s policies of appropriately reducing regulatory burden, in general, with respect to individuals, businesses and others, and from the ACA specifically.

Second, not pursuing any regulatory change would be inconsistent with various court rulings that have rejected or undermined the legal positions taken by the Department in the 2016 Rule. It would not, for example, ensure that the text of the Code of Federal Regulations accurately reflects the *vacatur* of the provisions including gender identity and termination of pregnancy as prohibited grounds of discrimination on the basis of sex. It also would not account for the decision of the Northern District of Illinois that the “plain and unambiguous” statutory text of Section 1557 indicated that a plaintiff could only use the enforcement mechanism of the underlying civil rights statute that corresponds to its claim. *Briscoe v. Health Care Serv. Corp.*, 281 F. Supp. 3d 725, 737–38 (N.D. Ill. 2017) (dismissing a Section 1557 claim for sex discrimination using a disparate impact standard, because plaintiffs cannot bring disparate impact claims under Title IX); *accord Galuten on Behalf of Estate of Galuten v. Williamson Med. Ctr.*, 2019 WL 1546940, at * (M.D. Tenn. Apr. 9, 2019); *E.S. by and through R.S. v. Regence BlueShield*, 2019 WL 4566053, at *4 (W.D. Wash. Sept. 24, 2018); *but see Rumble v. Fairview Health Servs.*, No. 14–cv–2037 (SRN/FLN) (D. Minn. Mar. 16, 2017) (declining to determine the specific standard on a motion to dismiss and rejecting the implication that Congress meant to create a “new anti-discrimination framework completely ‘unbound by the jurisdiction of the four referenced statutes,’” but concluding Congress “likely” intended a single standard to avoid “patently absurd consequences”). In addition, it would fail to account for the decisions of Federal courts in California, New York, and Iowa that did not recognize disparate impact claims for sex discrimination under Section 1557, because such claims are not cognizable under Title IX. *See Condry v. UnitedHealth Group*, No. 3:17–cf–00183–VC (N.D. Calif. June 27, 2018) (Slip. Op. at 7); *Weinreb v. Xerox Business Services*, 323 F. Supp. 3d 501,

521 (S.D.N.Y. 2018); *York v. Wellmark, Inc.*, No. 4:16–cv–00627–RGE–CFB, Slip. Op. at *30 (S.D. Iowa Sep. 6, 2017). A court in Pennsylvania similarly indicated that there is no disparate impact claim for discrimination on the basis of race under Section 1557, because such claims are unavailable under Title VI. *See Southeastern Pennsylvania v. Gilead*, 102 F. Supp. 3d 688 (E.D. Pa. 2015); *but see Callum v. CVS Corp.*, 137 F. Supp. 3d 817 (D.S.C. 2015).

Third, the Department believes that the status quo would not address, much less remedy, public confusion regarding complainants’ rights and covered entities’ legal obligations. The Department believes that revisiting the rule will address inconsistencies between the Department’s underlying regulations and the regulations and actions taken by other components of the Government. As applied to sex discrimination claims, the 2016 Rule set forth a definition of discrimination on the basis of sex under Section 1557 implementing Title IX that varied from the practice of other Departments. If the Department uses interpretations of Title IX that differ from other Departments and from the legal interpretation of the U.S. Government as set forth by the Department of Justice, it could lead to inconsistent outcomes across complainants and covered entities, with the problem especially acute in cases involving a single covered entity being investigated with respect to the same allegations by multiple Departments that come to different conclusions on effectively the same question.

The Department also considered adding “gender identity” and “sexual orientation” to a definition of “sex” or “on the basis of sex” under Title IX. The Department concluded it is inappropriate to do so in light of the ordinary public meaning of discrimination on the basis of sex under Title IX. This final rule will also significantly restore the ability of States to establish policies in this area, based on their weighing of the competing interests at stake. As a policy matter, the Department believes State and local entities are better equipped to address with sensitivity issues of gender dysphoria, sexual orientation, and any competing privacy interests, especially when young children or intimate settings are involved. The Department’s position will not bar covered entities from choosing to grant protections on the basis of sexual orientation and gender identity that do not conflict with any other Federal law. The Department has also determined that economic incentives, performance objectives, or

other related forms of regulation are neither appropriate nor feasible solutions to the problems to be solved.

The Department also considered simply repealing the 2016 Rule *in toto* and not issuing a replacement regulation. Such an approach would be consistent with the Administration's goals of reducing the regulatory burden on covered entities, and is allowed under Section 1557, as that provision does not require the Department to issue implementing regulations. However, the Department is committed to vigorous enforcement of civil rights and nondiscrimination laws as directed by Congress, and considers it worthwhile to set forth that commitment in a Section 1557 regulation which takes the position that the Department will use the enforcement mechanisms available under the statutes cited in Section 1557 and their underlying regulations. Additionally, the Department believes that certain provisions—such as those addressing the assurance of compliance with Section 1557, effective communication and accessibility for individuals with disabilities, and certain language access services—address applications of civil rights laws without the statutory or legal conflicts, or excessive regulatory burdens, entailed by other provisions of the current Rule.

The Department also considered retaining the provision on visual standards for video remote interpreting services for LEP individuals. However, the burden of requiring covered entities to provide video technology training and utilize expensive software does not appear to be justified based on minimal benefit to language speakers who can effectively communicate when there is clear audio transmission through the remote interpreting service.

Accordingly, the Department believes it is appropriate to clarify how OCR will enforce the ACA's nondiscrimination protections by replacing the 2016 Rule with regulatory provisions (1) applying the enforcement mechanisms provided under the civil rights statutes and related implementing regulations cited in Section 1557 to the contexts identified in Section 1557, (2) vesting enforcement authority under Section 1557 with the Director of the Office for Civil Rights, and (3) specifying how Section 1557 enforcement shall interact with existing laws—while retaining certain language and disability access provisions and the assurances provision.

With respect to the requirement that covered entities provide nondiscrimination notices and taglines, the Department considered keeping the

requirement but limiting the frequency of required mailings to one per year to each person served by the covered entity. To estimate the cost of this option, the Department adopted the base assumptions described in this Regulatory Impact Analysis regarding the number of covered entities and the average unit cost associated with the low-end and high-end costs of a notice and taglines mailing (materials, postage, and labor).³¹⁹ The Department adjusted the volume of mailings based on the average number of individuals served by each covered entity.³²⁰ The Department assumed the same covered entity compliance rate for the insurance industry as under this Regulatory Impact Analysis but assumed an increased compliance rate for non-insurers (assuming 30% instead of 10%) to reflect that more entities would likely comply with the requirements if the burden were to be significantly reduced to one mailing per customer/patient per year. Based on this method, the estimated total cost of this alternative is approximately \$63 million per year. Although this option poses a significantly reduced burden, the Department believes the costs under this alternative still outweigh the benefits because such mass multi-language taglines mailings would still be received overwhelmingly by English speakers and because the requirement to issue nondiscrimination notices would be largely duplicative of nondiscrimination notice requirements that already exist under Section 1557's underlying civil rights regulations.³²¹

(2) Considerations for Cost-Effective Design

In this final rule, the Department replaces much of the 2016 Rule, to significantly reduce regulatory burdens and to return to the longstanding understanding of the underlying nondiscrimination obligations imposed by the civil rights laws referenced in Section 1557.

³¹⁹ The average of the low (\$0.035) and high (\$0.32) unit costs is \$0.18 per notice and tagline mailing.

³²⁰ The estimated volume is expected to vary based on covered entity type. For instance, each of the 180 health insurance issuers serve 685,138 individuals on average, based on the number of insured individuals (123 million), which equates to 685,138 mailings per issuer. Each of the 185,649 physicians' offices serve 1,703 individuals, based on the average number of individuals (316 million) associated with 990 million physicians visits. On average, each covered entity serves about 3,000 persons per entity, which equates to 3,000 mailings per entity, based on 820 million persons served by 275,002 covered entities.

³²¹ See 45 CFR 80.6(d) (Title VI), 84.8 (Section 504), 86.9 (Title IX), 91.32 (Age Act).

In the preamble to the 2016 Rule, the Department observed that there were pre-existing requirements under Federal civil rights laws that, "except in the area of sex discrimination," applied to a large percentage of entities covered by the 2016 Rule. 81 FR at 31446. Thus, in the 2016 Rule the Department concluded it did not expect covered entities to undertake additional costs with respect to that rule's prohibitions on discrimination on the basis of race, color, national origin, age, or disability, "except with respect to the voluntary development of a language access plan." *Id.*

By finalizing this rule without the 2016 Rule's definition of sex discrimination and eliminating the requirements regarding notices, taglines, and visual standards in video remote interpreting services for LEP individuals, language access plans, and duplicative grievance procedures, the final rule also allows covered entities the freedom to order their operations more efficiently, more flexibly, and in a more cost-effective manner.

Accordingly, returning to the familiar longstanding requirements is a cost-effective way of (1) removing the unjustified burdens imposed by the 2016 Rule; (2) reducing confusion among the public and covered entities; (3) promoting consistent, predictable, and cost-effective enforcement; and (4) creating space for innovation in the provision of compliant services by covered entities (including flexible and innovative language access practices and technology), while faithfully and vigorously enforcing Section 1557's civil rights protections.

(3) Methodology for Cost-Benefit Analysis

For purposes of this Regulatory Impact Analysis (RIA), the final rule adopts the list of covered entities and other cost assumptions identified in the 2016 Rule's RIA and that of the 2019 proposed rule. The use of assumptions from the 2016 Rule in the present RIA, however, does not mean that the Department adopts those assumptions in any respect beyond the purpose of estimating (1) the number of covered entities that would be relieved of burden, and (2) cost relief. For example, the 2016 Rule based several cost estimates on an expansive definition of Federal financial assistance, which significantly impacted the number of covered entities currently burdened by the 2016 Rule; thus, it is appropriate to use that definition for estimating cost relief. Such use, however, should not be interpreted as an endorsement or

acceptance of the definition for any other purpose.

The Department also does not “carry over” every assumption from the 2016 Rule for this final rule’s RIA calculation. Most notably, the Department no longer considers its prior estimates of costs imposed due to the 2016 Rule’s taglines requirement to be accurate or valid, and provides a more thorough and accurate estimate for purposes of this final rule.

Cost savings result from the repeal of (1) the provision on the incentive for covered entities to develop language access plans and (2) the provisions on notice and taglines. In addition, the Department quantitatively analyzes and monetizes the impact that this final rule may have on covered entities’ voluntary actions to re-train their employees on, and adopt policies and procedures to implement, the legal requirements of this final rule. The Department analyzes the remaining benefits and burdens qualitatively because of the uncertainty inherent in predicting other concrete actions that such a diverse scope of covered entities might take in response to this final rule.

The Department also considered the public comments submitted in response to the proposed rule. The Department appreciates the information and various perspectives provided in those comments, which are summarized

below and for which responses are provided.³²²

(4) Cost-Benefit Analysis

a. Overview

In the 2016 Rule, the Department estimated \$942 million³²³ in costs (over five years) due to impacts on personnel training and familiarization, enforcement, posting of nondiscrimination notices and taglines, and revisions in covered entity policies and procedures. 81 FR 31446, and 31458–59 (at Table 5). As stated earlier, the Department estimated in the 2016 Rule that these costs would arise *primarily* from requirements imposed by the 2016 Rule with which covered entities were not already complying.³²⁴ The Department specifically identified the 2016 Rule’s interpretation of sex discrimination to cover gender identity and sex stereotyping,³²⁵ and the 2016 Rule’s consideration of language access plans for compliance purposes, as provisions triggering the imposition of new costs.³²⁶ See 81 FR 31459—Table 5.

In 2016, the Department estimated that the 2016 Rule’s nondiscrimination notice requirement would impose approximately \$3.6 million in one-time additional costs on covered entities. 81 FR 31469. Regarding these requirements, the Department stated: “We are uncertain of the exact volume

of taglines that will be printed or posted, but we estimate that covered entities will print and post the same number of taglines as notices and therefore the costs would be comparable to the costs for printing and disseminating the notice, or \$3.6 million.” 81 FR 31469. Thus, the total notice and taglines cost was estimated at \$7.2 million in the first year and was predicted to go down to zero after year one, despite the regulatory requirement for covered entities to provide notices and taglines to beneficiaries, enrollees, and applicants by appending notices and taglines to all “significant publications and significant communications” larger than postcards or small brochures. *Compare* 81 FR 31458 (Table 5), *with* 45 CFR 92.8.

For reasons explained more fully below, the 2016 estimate of \$7.2 million in one-time costs stemming from the notice and taglines requirement was a gross underestimation, and thus this final rule’s elimination of those requirements would generate a large economic benefit of approximately \$2.9 billion over five years on the repeal of the notice and taglines provision.

Table 1 shows the expected cost savings from the repeal of the notice and taglines provision and the quantified costs to firms for training and revising procedures and policies.

TABLE 1—ACCOUNTING TABLE OF ECONOMIC BENEFITS AND COSTS OF ALL FINALIZED CHANGES
[In millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Savings:						
Total (undiscounted)	\$643	\$614	\$585	\$556	\$528	\$2,926
Total (3%)	624	579	536	494	455	2,688
Total (7%)	601	536	478	425	376	2,416
Costs—Quantified Costs:						
Total (undiscounted)	276	0	0	0	0	276
Total (3%)	269	0	0	0	0	269
Total (7%)	259	0	0	0	0	259
Net Total (undiscounted 3% 7%)	2,650 \$2,319 (3%) \$2,157 (7%)

Non-quantified benefits and costs are described below.

³²² The population, labor, and similar statistical data used in this RIA are also not changed from those used in the RIA in the proposed rule, because updating that data from the time of the proposed rule in June 2019 to the time of the publication of this final rule would not lead to substantive changes in the analysis.

³²³ Throughout the regulatory impact analysis in the 2016 Rule, the 2016 estimates used 2014 dollars unless otherwise noted.

³²⁴ 81 FR 31446 (“to the extent that certain actions are required under the final rule where the

same actions are already required by prior existing civil rights regulations, we assume that the actions are already taking place and thus that they are not a burden imposed by the rule”).

³²⁵ 81 FR 31455 (“Although a large number of providers may already be subject to state laws or institutional policies that prohibit discrimination on the basis of sex in the provision of health services, the clarification of the prohibition of sex discrimination in this regulation, particularly as it relates to discrimination on the basis of sex stereotyping and gender identity, may be new.”).

³²⁶ Although the 2016 Rule did not require covered entities to develop a language access plan, the Rule stated that the development and implementation of a language access plan is a factor the Director “shall” take into account when evaluating whether an entity is in compliance with Section 1557. 45 CFR 92.201(b)(2). Therefore, the Department anticipated that 50% of covered entities would be induced to develop and implement a language access plan following issuance of the 2016 Rule. 81 FR 31454.

b. Generally Applicable Benefits and Burdens

i. Simplification and Flexibility

This final rule would result in other tangible benefits for covered entities. First, because this final rule is simpler and more easily administrable, it would be less likely that covered entities will need to pay for legal advice or otherwise expend organizational resources to understand their obligations under Section 1557, either in general or with respect to any particular situation that arises. Second, this final rule reduces the need for covered entities to expend labor and money on an ongoing basis to maintain internal procedures for mitigating the legal risk that persists due to unresolved controversy over the meaning of Section 1557. The Department solicited comment regarding the nature and magnitude of such ongoing costs incurred by covered entities, and below the Department summarizes and responds to significant comments regarding the regulatory impact of changes to the notice and taglines requirements.

This final rule will also carry intangible benefits, including that covered entities would enjoy increased freedom to adapt their Section 1557 compliance programs to most efficiently address their particular needs, benefiting both covered entities and individuals. The value of knowledge of civil rights is difficult to quantify. Covered entities will be free under the final rule to implement policies and procedures that comply with Federal civil rights laws in creative, effective, and efficient ways that are tailored to the covered entities and the communities that they serve.

ii. Policies and Procedures Concerning Gender Identity

In the proposed rule, the Department anticipated that the 2016 Rule likely induced many covered entities to conform their policies and operations to reflect gender identity as a protected category under Title IX. The Department requested and received public comments on the possible benefits and burdens related to changes in the proposed rule.

Comment: Many commenters contended that the proposed rule would lead covered entities to remove protections from transgender individuals in their policies and procedures. Commenters contended that these changes would lead to a wide range of burdensome results, including discrimination on the basis of gender identity and resulting negative health consequences, increased costs for

treatment of such conditions, cost-shifting to transgender individuals, and increased burdens on the public health system due to the changes. Commenters also contended that similar results would occur from the Department's decision not to include sexual orientation nondiscrimination provisions in the proposed rule.

Response: The Department does not believe that this final rule will lead to significant burdens on entities due to changes to the gender identity language from the 2016 Rule, nor that the commenters have identified sufficient data to show that these negative consequences will occur or the extent to which they will occur. In December 2016, the *Franciscan Alliance* court preliminarily enjoined the gender identity provisions of the 2016 Rule on a nationwide basis, and more recently the court vacated those provisions. Consequently, this final rule's revisions to the provisions addressing gender identity do not change covered entities' obligations. Therefore, even though some entities may have changed their policies and procedures at the outset of the 2016 Rule, the Department concludes that because the gender identity provisions of the 2016 Rule have been vacated prior to this rule being finalized, it is even less likely than at the time of the proposed rule that this final rule will lead to changes in policies and procedures concerning gender identity. In addition, as explained above, the 2016 Rule did not include language prohibiting discrimination on the basis of sexual orientation status standing alone as a form of sex discrimination. The Department therefore does not anticipate any material change to covered entities' policies concerning sexual orientation as a result of this final rule.

In addition, it is worth noting that many covered entities are located in jurisdictions that prohibit sexual orientation and gender identity discrimination under State or local laws. Therefore, such entities are unlikely to change their policies, training, or grievance procedures concerning gender identity as a result of this final rule. Moreover, nothing in this final rule, or in the court decisions, prohibits entities from maintaining gender identity nondiscrimination policies and procedures voluntarily, and the Department believes some covered entities will continue to do so.

If some entities change their policies and procedures based on this final rule, such a reversion may entail amending organizational nondiscrimination policies and training materials, and

communicating those changes to employees. The process of voluntarily reverting to previous practices would likely result in net cost savings to covered entities. Otherwise these entities likely would not take such action. In addition, the Department believes that, if this final rule led to covered entities changing policies and procedures, some covered entities may no longer incur costs associated with processing grievances related to gender identity discrimination under Title IX, because such claims will not be cognizable under this final rule.

The Department, however, is uncertain as to the total number of covered entities that will change their policies and grievance processes to reflect the changes in this final rule. The reasons for this uncertainty include, as stated above, the fact that such changes would only be indirectly attributable to this rule, not caused by this rule, because previous court rulings have negated the gender identity provisions from the 2016 Rule for over three years, and this rule has no effect on State and local gender identity protections. The Department is not aware of data about how many entities might change their policies for these indirect reasons.

Similarly, the Department also lacks the data necessary to estimate the number of individuals who currently benefit from covered entities' policies governing discrimination on the basis of gender identity who would no longer receive those benefits after publication of this rule—nor data to estimate how many of those individuals may experience the workplace and health-related negative consequences that many commenters contend will result from this final rule. The Department similarly lacks data to estimate what greater public health costs, cost-shifting, and expenses may result from entities changing their nondiscrimination policies and procedures after promulgation of this rule. The Department reiterates that it believes these effects will be minimal, again due to the fact that gender identity provisions were vacated from the 2016 Rule by the *Franciscan Alliance* court before this rulemaking was finalized.

c. Baseline Assumptions

The following discussion identifies the economic baselines from which the Department measures the expected costs and benefits of this final rule. Its baselines includes the cost estimates in the 2016 Rule, in addition to data it has gathered since the 2016 Rule was implemented, as described in more detail below. The Department also considered public comments, and

responds to significant comments in this discussion.

Key assumptions track those set forth in the proposed rule and include the following: (1) The 2016 Rule triggered significant activity on the part of covered entities, generating both costs and benefits; (2) under the December 2016 nationwide preliminary injunction in *Franciscan Alliance*, and the October 2019 final judgment in that case, the gender identity and termination of pregnancy provisions of the 2016 Rule have been unenforceable and are now absent from the 2016 Rule, without regard to whether this rule is finalized; (3) covered entities were already generally complying with civil rights laws and related regulations that were in effect before the 2016 Rule, and so this final rule generally does not impose any new burden beyond those imposed prior to the issuance of the 2016 Rule;³²⁷ (4) the projected costs from the 2016 Rule for years 1 and 2 have been incurred, and the projected costs from years 3, 4, and 5 have not been incurred; (5) repeal of the 2016 Rule's notice and taglines requirements does not affect notice or taglines requirements required by CMS guidance or regulations that do not reference, rely on, or depend upon the taglines requirements of the 2016 Rule; (6) a relatively small percentage of physicians and hospitals currently append notices and taglines to billing statements sent to patients, while all insurance companies append notices and taglines to their explanations of benefits statements; and (7) covered employers are more likely to train employees who interact with the public than those who do not.

³²⁷ OMB Circular A-4 discusses the practice whereby an RIA for a rule codifying a policy may include the impacts of that policy, even if the effects follow directly from an action by another branch of the federal government. The Circular notes that: "In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing, even in the absence of the regulatory action. In these cases, you should use a pre-statute baseline. If you are able to separate out those areas where the agency has discretion, you may also use a post-statute baseline to evaluate the discretionary elements of the action." Although a baseline established prior to the *Franciscan Alliance* court's December 2016 and October 2019 orders would be considered analogous to the pre-statute baseline discussed in Circular A-4, given the existence of the RIA for the 2016 Rule, an assessment relative to a pre-*Franciscan Alliance* baseline would add little to the body of relevant analysis, and the longstanding duration of the court orders contributes to a lack of new data pertaining to certain alleged effects of language falling under those orders. For these reasons, the baseline established after December 2016, which isolates the effects most directly attributable to certain elements of this rule's finalization, is emphasized throughout the relevant parts of this RIA.

d. Covered Entities

i. Entities Covered by Section 1557

The 2016 Rule and this final rule apply to any entity that has a health program or activity, any part of which receives Federal financial assistance from the Department, any program or activity administered by the Department under Title I of the ACA, or any program or activity administered by an entity established under such Title. Covered entities under the 2016 Rule's definition³²⁸ include the following:

(A) Entities With a Health Program or Activity, Any Part of Which Receives Federal Financial Assistance From the Department

The RIA for the 2016 Rule stated that the Department, through agencies such as the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare & Medicaid Services (CMS), provides Federal financial assistance through various mechanisms to health programs or activities of local governments, State governments, and the private sector. An entity may receive Federal financial assistance from more than one component in the Department. For instance, Federally qualified health centers receive Federal financial assistance from CMS by participating in Medicaid programs and may also receive Federal financial assistance from HRSA through grant awards. Because more than one funding stream may provide Federal financial assistance to an entity, the examples we provide may not uniquely capture entities that receive Federal financial assistance from only one component of the Department. Under the 2016 Rule, the covered entities consisted of the following:

(i) Entities receiving Federal financial assistance through their participation in Medicare (excluding Medicare Part B) or Medicaid (about 133,343 facilities).³²⁹ Examples of these entities cited in the 2016 Rule's RIA include:

- Hospitals (includes short-term, rehabilitation, psychiatric, and long-term)

³²⁸ As noted above, we use the list and number of covered entities and other figures from the 2016 Rule's RIA in this RIA for the sake of consistency and convenience, but such use does not mean that we adopt or accept any of the underlying analysis, definitions, or assumptions from the 2016 Rule's RIA for any other purpose related to this final rule.

³²⁹ CMS, Provider of Service file (June 2014), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/POS2014.html>.

- Skilled nursing facilities/nursing facilities (facility-based and freestanding)
- Home health agencies
- Physical therapy/speech pathology programs
- End-stage renal disease dialysis centers
- Intermediate care facilities for individuals with intellectual disabilities
- Rural health clinics
- Physical therapy—-independent practice
- Comprehensive outpatient rehabilitation facilities
- Ambulatory surgical centers
- Hospices
- Organ procurement organizations
- Community mental health centers
- Federally qualified health centers.

(ii) Laboratories that are hospital-based, office-based, or freestanding that receive Federal financial assistance through Medicaid payments for covered laboratory tests (about 445,657 laboratories with Clinical Laboratory Improvement Act certification).

(iii) Community health centers receiving Federal financial assistance through grant awards from HRSA (1,300 community health centers).³³⁰

(iv) Health-related schools in the United States and other health education entities receiving Federal financial assistance through grant awards to support 40 health professional training programs that include oral health, behavioral health, medicine, geriatric, and physician's assistant programs.³³¹

(v) State Medicaid agencies receiving Federal financial assistance from CMS to operate CHIP (includes every State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(vi) State public health agencies receiving Federal financial assistance from CDC, SAMHSA, and other HHS components (includes each State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(vii) QHP issuers receiving Federal financial assistance through advance payments of premium tax credits and cost-sharing reductions (which include at least the 169 health insurance issuers in the Federally-facilitated Exchanges receiving Federal financial assistance

³³⁰ HRSA, Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, <http://www.hrsa.gov/about/budget/budgetjustification2016.pdf>.

³³¹ HRSA, Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, <http://www.hrsa.gov/about/budget/budgetjustification2016.pdf>.

through advance payments of premium tax credits and cost-sharing reductions, and at least 11 health insurance issuers operating in the State Exchanges).³³²

(viii) Physicians receiving Federal financial assistance through Medicaid payments, “meaningful use” payments, and other sources, but not Medicare Part B payments (Medicare Part B payments to physicians are not Federal financial assistance). The Medicare Access and CHIP Reauthorization Act amended Section 1848 of the Act to sunset “meaningful use” payment adjustments for Medicare physicians after the 2018 payment adjustment.

In the 2016 Rule, the Department estimated that that rule likely covered almost all licensed physicians because they accept Federal financial assistance from sources other than Medicare Part B. Many physicians participate in more than one Federal, State, or local health program that receives Federal financial assistance, and many practice in several different settings, which increases the possibility that they may receive payments constituting Federal financial assistance.

For the sake of consistency and convenience, the Department uses the 2016 Rule’s RIA estimate of the number of physicians receiving Federal financial assistance. As the 2016 Rule RIA noted, based on 2010 Medicaid Statistical Information System data (the latest available), about 614,000 physicians accept Medicaid payments and are covered under Section 1557 as a result.³³³ This figure represents about 69% of licensed physicians in the United States, based on the 890,000 licensed physicians reported in the Area Health Resource File.³³⁴ In addition, physicians receiving Federal payments from non-Part B Medicare sources will also come under Section 1557. The 2016 RIA noted that, as of January 2014, 296,500 Medicare-eligible professionals had applied for funds to support their “meaningful use” technology efforts.³³⁵

³³² Qualified Health Plans Landscape Individual Market Medical (2015), <https://data.healthcare.gov/dataset/2015-QHP-Landscape-Individual-Market-Medical/mp8z-jtg7>.

³³³ John Holahan and Irene Headen, Kaiser Commission on Medicaid and the Uninsured, Medicaid Coverage and Spending in Health Reform: National and State-by-State Results for Adults at or Below 133% FPL (2010), <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/medicaid-coverage-and-spending-in-health-reform-national-and-state-by-state-results-for-adults-at-or-below-133-fpl.pdf>. Estimates are based on data from FY 2010 MSIS.

³³⁴ HRSA, Area Health Resource Files (2015), <http://ahrh.hrsa.gov>.

³³⁵ Mynti Hossain and Marsha Gold, Mathematical Policy Research Inc.: Prepared for The Office of the National Coordinator for Health Information Technology, HHS, Monitoring National

Adding the approximately 614,000 physicians who receive Medicaid payments to the 296,500 physicians who receive meaningful use payments would yield over 900,000 physicians potentially reached by Section 1557 because they participate in Federal programs other than Part B of Medicare. Because physicians can receive both Medicaid and meaningful use payments, and these figures are not adjusted for duplication, the 900,000 result is best interpreted as an upper bound.

When the Department compared the upper-bound estimated number of physicians participating in Federal programs other than Medicare Part B (over 900,000) to the number of licensed physicians counted in HRSA’s Area Health Resource File (approximately 890,000), and allowing for duplication in both the Medicare/Medicaid and HRSA numbers,³³⁶ the Department concluded in the 2016 Rule RIA that almost all practicing physicians in the United States are reached by Section 1557 because they accept some form of Federal remuneration or reimbursement apart from Medicare Part B.

(B) Programs or Activities Administered by the Department Under Title I of the ACA

This final rule applies to programs or activities administered by the Department under Title I of the ACA. Such programs or activities include temporary high-risk pools (section 1101), temporary reinsurance for early retirees (section 1102), Department mechanisms for identifying affordable health insurance coverage options (section 1103), the wellness program demonstration project (section 1201, adding Public Health Service (PHS) Act 2705(j)), the provision of community health insurance options (section 1323), and the establishment of risk corridors for certain plans (section 1342).

(C) Entities Established Under Title I of the ACA

This final rule applies to the health insurance exchanges established under Title I of the ACA. Such exchanges currently include the 12 State Exchanges (and D.C. Exchange), six State Exchanges on the Federal platform and 32 Federally-facilitated Exchanges.³³⁷ Title I additionally

Implementation of HITECH: Status and Key Activity Quarterly Summary (Jan. to Mar. 2014), http://www.healthit.gov/sites/default/files/global-evaluationquarterlyreport_january-march2014.pdf.

³³⁶ The Area Health Resource File itself double counts physicians who are licensed in more than one State.

³³⁷ CMS, State-Based Exchanges for Plan Year 2018 (Nov. 1, 2019), <https://www.cms.gov/CCIIO/>

establishes State advisory councils concerning community health insurance (section 1323) and certain reinsurance entities under the transitional reinsurance program (section 1341).

ii. Entities Covered by Title IX

Title IX applies to recipients of Federal financial assistance for education programs or activities. 20 U.S.C. 1681. The population of applicable covered entities is defined by the term “recipient” in the Department’s Title IX regulations. The population includes any State or political subdivision thereof, or any instrumentality of a State or political subdivision thereof, any public or private agency, institution, or organization, or other entity, or any person, to whom Federal financial assistance is extended directly or through another recipient and that operates an education program or activity that receives such assistance, including any subunit, successor, assignee, or transferee thereof. *See, e.g.*, 45 CFR 86.2. Under the definition of program or activity, recipients of Federal financial assistance within the scope of Title IX may include colleges, universities, local educational agencies, vocational education systems, or other entities or organizations principally engaged in the business of providing education. *See, e.g.*, 45 CFR part 86, App. A (cross-referencing Appendix B to 45 CFR part 80).

e. Cost Savings From Eliminating Notice and Taglines Requirement

The Department’s baseline for calculating the savings from repealing the notice and taglines requirement includes approximately \$585 million in additional average annual costs (over the next five years) that were not considered in the 2016 Rule. It is important to note that, while industry estimates prompted the Department to reassess the burdens imposed by the 2016 Rule, the Department conducted and relied upon its own cost analysis in developing the RIA for this final rule.

The 2016 Rule estimated \$7.1 million for covered entities and \$70,400 for the Federal government in combined annual costs for printing and distributing nondiscrimination notices and taglines, with the costs being apportioned roughly equally between notices and taglines. 81 FR at 31453. As explained in detail below, the Department estimates the combined notice and taglines requirement has actually cost

Resources/Fact-Sheets-and-FAQs/state-marketplaces.html.

covered entities hundreds of millions of dollars per year.

The 2016 Rule requires covered entities to include a notice and taglines for any “significant” document or publication, but did not define the term “significant.” 45 CFR 92.8(f)(1)(i).³³⁸ Thus, covered entities have interpreted this provision to require a notice and taglines to accompany many communications from covered entities, including annual benefits notices, medical bills from hospitals and doctors, explanations of benefits from health insurance companies or health plans, and communications from pharmacy benefit managers.

This led to an extraordinary amount of mailed or electronically delivered communications by entities such as plan administrators and pharmacy benefit managers, including with every auto-ship refill reminder, formulary notice, and specialty benefit letter. Further, some other entities that operate in multiple States have interpreted the 2016 Rule as requiring them to include taglines for as many as 60 languages, or have included that many taglines in mailed or electronically-delivered communications due to the cost or technical barriers to customizing mailing inserts on a State-by-State basis, and thus have incurred costs to send up to an additional two double-sided pages of notices with each communication.³³⁹

To estimate the volume of notices and taglines that accompany an annual benefits notice, we began with the approximately 300 million persons in the United States who have health insurance,³⁴⁰ or approximately 91% of the U.S. population. The Department then assumed that the annual notice of benefits (that includes a notice and

taglines) is sent to each policyholder, not to each individual member of a covered household, such as covered children. Of the total U.S. population, 306 million individuals belong to 117.7 million households. For the data set relied on, a “household” includes “all the people who occupy a housing unit The occupants may be a single family, one person living alone, two or more families living together, or any other group of related or unrelated people³⁴¹ who share living arrangements.”³⁴² By implication, 17.3 million individuals do not belong to a household,³⁴³ and live in group quarters.³⁴⁴ The Department assumed that the percentage of the U.S. population that is uninsured, 9%, is the same percentage of U.S. individuals belonging to U.S. households that are uninsured. To calculate the number of annual benefits notices, the Department added the total number of individuals that do not belong to a household (17.3 million) to the total number of households (117.7 million), and discounted the sum (135 million) by 9% to exclude those individuals who are not insured. The total number of annual notices of benefits that include a nondiscrimination notice and taglines is therefore approximately 123 million (approximately 91% of 135 million).

To estimate the volume of notices and taglines that accompany communications from the health insurance Exchanges, the Department assumes the Exchanges send communications to the 11.8 million

individuals enrolled in the individual market.³⁴⁵ It assumes that the Exchanges send out approximately 1.5 notices per person per year. This accounts for the annual re-enrollment communication plus additional communications Exchanges will send for special enrollment periods. Thus, the total estimated volume of notices and taglines attributable to the Exchanges is 17.7 million.

To estimate the volume of notices and taglines that accompany hospital bills and explanations of benefits sent by insurance companies (or health plans) for hospital admissions, the Department first estimated the total number of hospital bills and explanation of benefits that would be sent to patients annually. There are 35 million hospital admissions per year.³⁴⁶ For the purpose of this estimate, the Department assumes that each admission generates three bills from one hospital visit—each of which would include a notice and taglines document, for a total of 105 million bills, assuming three bills per admission.³⁴⁷ The Department assumes that 10% of the 105 million bills will have a notice and taglines document attached, for a total of 10.5 million notice and taglines documents.

For patients who were insured upon admission to the hospital, in addition to the three hospital bills they would receive (on average), they would receive three associated explanations of benefits from their insurer or health plan, each of which would also include notice and taglines documents. If more than three service providers bill a patient for a hospital visit, then the savings associated with this patient encounter will be greater than estimated due to the additional notice and taglines documents that the insurer would send with each additional explanation of benefits beyond the initial three assumed. If fewer than three service providers bill for a hospital visit, then the savings will be less due to the decreased volume of notice and taglines documents that the insurer would send because the insurer would send fewer than three explanation of benefits. Given that approximately 91% of the U.S. population is insured, the

³³⁸ After publishing the 2016 Rule, OCR issued guidance explaining that any significant publication printed on an 8.5 x 11 sheet of paper is not considered small sized and, thus, must include a minimum of 15 taglines. See OCR, Question 23, General Questions about Section 1557 (May 18, 2017), <https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html>.

³³⁹ Although OCR has issued guidance stating that a covered entity may identify the top 15 languages spoken across all the States that the entity serves, See https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/aggregation_tagline/index.html, evidence of notices that some covered entities shared with OCR suggests covered entities with beneficiaries in multiple States may issue more comprehensive tagline notices with more than 15 languages, likely because of reasonable interpretations of the relevant provisions of the 2016 Rule, and the higher cost of attempting to tailor notices and taglines to individuals based on their specific State.

³⁴⁰ Calculated by subtracting total uninsured population (28.1 million as of 2016). See <https://www.census.gov/library/publications/2017/demo/p60-260.html>, from the total U.S. Population (327 million as of March 14, 2018). See <https://www.census.gov/popclock>.

³⁴¹ The calculations do not take into account households where two or more unrelated persons have individual coverage, and thus receive separate annual notices at the same household. The Department believes, however, that this exclusion has only a minor impact on the overall figures.

³⁴² U.S. Census Bureau, American Community Survey and Puerto Rico Community Survey 2016 Subject Definitions 76, https://www2.census.gov/programs-surveys/acs/tech_docs/subject_definitions/2016_ACSSubjectDefinitions.pdf (defining “household” under “Household Type and Relationship”).

³⁴³ The Department subtracted 306 million individuals belonging to a household from the total U.S. population of 323.4 million individuals. See U.S. Census Bureau, <https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk> (relied on 2016 population nationally).

³⁴⁴ U.S. Census Bureau, American Community Survey and Puerto Rico Community Survey 2016 Subject Definitions 76, https://www2.census.gov/programs-surveys/acs/tech_docs/subject_definitions/2016_ACSSubjectDefinitions.pdf (“People not living in households are classified as living in group quarters.”). “Group quarters include . . . college residence halls, . . . skilled nursing facilities, . . . correctional facilities, and workers’ dormitories.” U.S. Census Bureau, 2016 American Community Survey/Puerto Rico Community Survey Group Quarters Definitions, 1 https://www2.census.gov/programs-surveys/acs/tech_docs/group_definitions/2016GQ_Definitions.pdf.

³⁴⁵ See CMS, *Health Insurance Exchanges 2018 Open Enrollment Period Final Report* (Apr. 3, 2018), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-03.html>.

³⁴⁶ CDC, *Chartbook on Long-Term Trends in Health* (2016), <http://www.cdc.gov/nchs/data/atus/hus16.pdf#317>.

³⁴⁷ The Department presumes one hospital visit likely will generate a bill from the physician and two bills from any combination of services, such as anesthesia, ambulance service, imaging/radiology, or laboratory or blood work.

Department estimates that approximately 32 million of the 35 million hospital admissions are associated with insured patients (91% of 35 million hospital admissions).³⁴⁸ This assumption does not account for variation in healthcare consumption between the insured and uninsured populations. It is possible that more hospital admissions are attributable to the uninsured than the insured population. If such is the case, the Department's estimate for the number of notices and taglines attributable to explanations of benefits would be lower. Further, this estimate does not account for outpatient hospital visits, which would increase the volume of notices and taglines. Moreover, if the elderly, nearly all of whom are insured by Medicare, make up a disproportionate share of hospital admissions, the Department's estimate for the number of notices and taglines attributable to explanations of benefits would be higher.

As discussed further below, the Department assumes 100% of insurance companies are compliant with the notice and taglines requirement. Thus, approximately 96 million notice and taglines documents are attributable to the explanations of benefits sent by insurers (32 million admissions times three explanation of benefits). Using rounded values, approximately 107 million additional notices and taglines (96 million plus 11 million) are related to hospital admissions.

To estimate the volume of notices and taglines that accompany doctor's bills and explanations of benefits from a physician's visit, the Department relied on data showing that individuals visit physicians' offices approximately 990 million times each year.³⁴⁹ Given that approximately 9%³⁵⁰ of Americans are uninsured, the Department assumes (and subtracting an estimated 5% for uninsured patients who do not visit the doctor, except in an emergency) that

95% of individuals who see doctors every year are insured in some form. The Department assumes that each visit to a compliant doctor's office will generate at least one bill from the doctor and at least one explanation of benefits from the health insurance company. As explained below, it also assumes that 10% of doctors and 100% of insurance companies comply with the notice and taglines requirement. Thus, approximately 99 million notices and taglines are attributable to doctors billing the patients directly, and approximately 941 million are attributable to explanations of benefits sent by insurers, which results in a total of 1.04 billion additional notices and taglines related to physician visits.

Because experience and substantial feedback from healthcare insurers suggests a very high degree of compliance with the notice and taglines requirements when it comes to documents such as explanations of benefits, the Department presumes 100% compliance for purposes of this RIA. Anecdotal evidence, however, suggests that hospital and physician compliance with the notice and taglines requirements in the documents discussed above is not standard industry practice. The Department estimates that, at most, 10% of such covered entities include notices and taglines in their significant mailed communications with patients. Although, according to the 2016 Rule's RIA, most hospitals and physicians are covered entities under Section 1557, the Department believes their failure to adopt notices and taglines as a standard billing and communication practice may be due to the fact the notice and taglines requirement in the 2016 Rule mentions a duty to notify "beneficiaries, enrollees, applicants, and members of the public" and does not explicitly mention "patients." 45 CFR 92.8(a). Additionally, the preamble to the 2016 Rule explained that the notice and taglines requirement covered communications "pertaining to rights or benefits," which insurance companies have universally interpreted as applying to significant numbers of communications they send to beneficiaries. 81 FR at 31402. For these reasons, the Department's calculations presume a 10% compliance rate for hospitals and physicians and a 100% compliance rate by health insurance companies concerning the notice and taglines requirement as it relates to bills and explanations of benefits, respectively.

To estimate the volume of notices and taglines that accompany pharmacy-related communications, the

Department relied on estimates from the Pharmaceutical Care Management Association, which, due to the nature of its organization, obtained an estimated number of impacted beneficiaries from its member organizations.

Approximately 173 million beneficiaries are being impacted annually by the notice and taglines requirement, and these beneficiaries receive between 6 and 28 communications per year with an accompanying notice and taglines. The Department relied on the average of this estimate (17 communications per year per beneficiary) to determine that 2.9 billion prescription-related communications (e.g., communications from pharmacy benefit managers) are sent each year.³⁵¹

To calculate the costs of the notice and taglines requirement, the Department assumes that the underlying communication to which a nondiscrimination notice and taglines document is attached is a communication that is on average three sheets of paper or less. Combined with the nondiscrimination notice and taglines (which constitute another 1–4 sides of a page, that is, 1 sheet single-sided³⁵² to 2 sheets of paper double-sided), the total number of sheets of paper that would be transmitted is equivalent to 4–5 sheets of paper or less. The associated costs of the notice and taglines requirement are (1) materials, (2) postage, and (3) labor. Because of the uncertainty around some of the estimates, we report ranges for some values in this analysis.

For materials, the Department assumes that materials (paper and ink) per notice and taglines mailing insert will cost between \$0.025 and \$0.10. The Department assumes that low materials cost would be \$0.025 to print a 1-page notice and taglines on a single sheet of paper single-sided, and the high materials cost of \$0.10 to print a 4-page notice and taglines on 2 sheets of paper double sided.

For postage, the Department estimates that the additional weight of the notice

³⁴⁸ Calculated by subtracting total uninsured population (28.1 million as of 2016). See <https://www.census.gov/library/publications/2017/demo/p60-260.html>, from the total U.S. Population in 2016 (323,405,935). See <https://www.census.gov/popclock>. http://news.gallup.com/poll/225383/uninsured-rate-steady-fourth-quarter-2017.aspx?source=Well-Being&g_medium=newsfeed&g_campaign=tiles.

³⁴⁹ CDC, Ambulatory Care Use and Physician Office Visits (2016), <https://www.cdc.gov/nchs/fastats/physician-visits.htm>. As noted above, the Department relies on the 2016 RIA assumption that virtually all doctors receive Federal financial assistance and, thus, are subject to the 2016 Rule.

³⁵⁰ Calculated by subtracting total uninsured population (28.1 million as of 2016). See <https://www.census.gov/library/publications/2017/demo/p60-260.html>, from the total U.S. Population in 2016 (323,405,935). See <https://www.census.gov/popclock>.

³⁵¹ Source: Pharmaceutical Care Management Association (May 2, 2017), available at <https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0006>.

³⁵² Although this cost-benefit analysis assumes a lower-bound estimate that a notice of nondiscrimination and 15 taglines may be printed on one side of one sheet of paper, the Department believes that a notice of that length is likely noncompliant with the 2016 Rule requirement to be posted "in conspicuously-visible font size." See also OCR, Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements and Sample Nondiscrimination Statement: Discrimination is Against the Law (printed on two sides of one sheet of paper), <https://www.hhs.gov/sites/default/files/sample-ce-notice-english.pdf>.

and taglines inserts result in a range of no incremental postage costs (low-end) to \$0.21 per mailing (high-end). For instance, if an underlying communication is three sheets of paper or less, a covered entity's inclusion of one double-sided page (or shorter) of notice and taglines insert would likely weigh one ounce or less (approximately four letter-sized pages weigh one ounce).³⁵³ Consequently, in this scenario, the notice and taglines insert would not increase the total weight of the mailing beyond the one ounce of postage that a covered entity would already expect to incur. If, however, a covered entity included 2 sheets of paper double-sided containing the nondiscrimination notice and taglines, added to a communication of three sheets of paper or more, the total weight of the mailing would likely be at least five sheets of paper, and therefore over one ounce. The marginal cost of postage for each ounce is \$0.20.³⁵⁴

For labor, the Department estimates the burden to download, print, and include these notices and taglines with all significant communications for an office clerk (Occupation Code No. 43–9061) with a mean hourly wage of \$16.92/hour³⁵⁵ plus an additional \$16.92/hour in fringe benefits, or \$33.84/hour for labor costs.³⁵⁶ Based on experience, entities can manually fold and insert notices and taglines into envelopes at a rate of approximately 360 per hour. Entities that use commercial machines can fold and insert notices and taglines as fast as 5,400 envelopes per hour.³⁵⁷ The Department uses the average of 2,880 notices and taglines that can be folded and placed into an envelope in an hour. Under these assumptions, the unit labor cost per notice and taglines mailing is \$0.01.

Considering materials, postage, and labor, the per-unit cost for the notice and taglines insert ranges from \$0.035 at

the low end (for one single-sided sheet of paper of notice and taglines) to \$0.32 at the high end (for two double-sided sheets of paper of notice and taglines), if the Department assumes that the average underlying mailer is 3 sheets of paper.

In addition, the Department estimates that some of these costs would be mitigated absent this final rule, due to transitions to electronic delivery for some communications affected by the 2016 Rule. The Department estimated, in the RIA for the Proposed Rule, that electronic delivery would reduce costs of affected communications by approximately 10–20% absent this final rule, shifting linearly from 10% in the first year to 20% in the fifth year following implementation (in other words, increasing by 2.5 percentage points each year). Survey results from Cognizant³⁵⁸ indicate that 70 percent of respondents consider it important to be able to view medical care-related statements (e.g., explanation of benefits documents) electronically, and that 42 percent are able to do so currently. But the same survey found that “[a]doption rates are low for the digital services currently offered by health insurers, even for those that respondents rated as very important,” with “just about half of the members who were aware of” a given digital service having actually “used it.” According to another survey by InstaMed,³⁵⁹ 23% of providers offer some electronic billing, but even out of those providers who do, 58% still provide fewer than half of their bills electronically.³⁶⁰ Moreover, it is likely that younger generations are the ones currently enrolling in e-statements; given that a disproportionate amount of health care services and products, especially pharmaceuticals, are consumed by the elderly, the communications containing the notices and taglines affected by this rule may be relatively unlikely to use e-statements. Therefore, as one end of a range of electronic delivery estimates, the Department maintains the earlier assumption of 10 percent in the first year, growing linearly to 20 percent in the fifth year after finalization, and departs from the preliminary RIA’s assumption only in that the linear growth is extended past the fifth year.

At the opposite end of the range of estimates, the electronic delivery rate is assumed to be 21 percent upfront (reflecting the higher of the two survey results cited above, with adjustment to account for the fact that in those surveys, 50% or less of patients offered electronic delivery have been accepting it) and 42 percent in Year 5 (reflecting the same survey, without such adjustment), with subsequent increases continuing at 5.25 percentage points per year.

In combining the two input ranges for Table 2 below—the cost per printed and mailed communication and the electronic delivery rates—the low ends are used together and the high ends are used together, to reflect that entities facing relatively high costs for printed communications would have greater incentive to shift to electronic delivery where feasible. The primary estimates relied on for Table 1, however, use simply the midpoint of each of the two input ranges.

Electronic delivery would eliminate postage costs, but may to a certain extent merely shift the costs of paper and printing from the entity providing the communication to the consumer/beneficiary/patient, given that some consumer/beneficiary/patient recipients of electronic communications will print them out and incur costs for the paper and ink associated with doing so. The Department has not included such consumer/beneficiary/patient costs in its estimates.

The Department averages the low and high-end estimates to determine a primary estimate of annual cost savings, which results in average savings of approximately \$0.58 billion per year, over the first five years, after adjusting for electronic delivery.

As discussed above, the proposed rule noted that, with repeal of the 2016 Rule requirements, the Department assumed that two other regulatory requirements for taglines would also be fully repealed because they depend on, or refer to, the 2016 Rule for authority for the taglines requirement. The first is the requirement placed on Health Insurance Exchanges (see 45 CFR 155.205(c)(2)(iii)(A)), which the Department estimates issue 17.7 million communications per year, primarily through eligibility and enrollment communications. The second is the requirement placed on QHP issuers (see HHS Notice of Benefit and Payment Parameters for 2016; 2016 Rule, 80 FR 10750, 10788 (Feb. 27, 2015)), whose costs are incorporated into the volume calculations for annual notices of benefits, and explanations of benefits discussed in more detail above. Those

³⁵³ See “How Many Sheets of Paper Fit in a 1 Ounce Envelope for Mailing Purposes,” <https://www.reference.com/business-finance/many-sheets-paper-fit-1-ounce-envelope-mailing-purposes-84ba93a60789c2e1>.

³⁵⁴ See U.S. Postal Service Postage Rates, <https://www.stamps.com/usps/current-postage-rates/>.

³⁵⁵ BLS, Occupational Employment and Wages (May 2018), https://www.bls.gov/oes/2018/may/oes_nat.htm.

³⁵⁶ CMS estimates that the labor costs would be a one-time cost of \$16,244 for Medicaid managed care and a one-time cost of \$9,669 for CHIP managed care. The Department assumes for its calculations that the labor costs for the notice and tagline provisions are not one-time but are ongoing costs associated with the value of office clerks’ time printing and including the notices and taglines with significant publications and significant communications.

³⁵⁷ See, e.g., Pitney Bowes, “Folders and Inserters,” <https://www.pitneybowes.com/nz/folders-inserters.html>.

³⁵⁸ See <https://www.cognizant.com/InsightsWhitepapers/The-Digital-Mandate-for-Health-Plans-codex1760.pdf>.

³⁵⁹ See <https://www.instamed.com/white-papers/trends-in-healthcare-payments-annual-report/>.

³⁶⁰ See <https://www.cognizant.com/InsightsWhitepapers/The-Digital-Mandate-for-Health-Plans-codex1760.pdf> and <https://www.instamed.com/white-papers/trends-in-healthcare-payments-report-2018/>.

two other regulations have not yet been amended in this respect, but the Department clarified above that because those requirements inform entities they will be deemed in compliance if they are in compliance with the Section 1557 rule's notice and taglines requirement, and because the latter has now been repealed by this final rule, covered

entities do not need to independently comply with those two other regulatory requirements cross referencing the Section 1557 rule. As a result, these estimates continue to assume this final rule will result in cost savings with respect to those requirements.

The Department also assumes that health insurance entities would not

voluntarily append notices and taglines to routine monthly premium statements absent the 2016 Rule, but are doing so because of it (or because of a requirement in another regulation that bases its requirement on the 2016 Rule's requirement).

TABLE 2—ANNUAL SAVINGS FROM REPEAL OF REQUIREMENT TO PUBLISH AND MAIL NOTICES AND TAGLINES, BY VOLUME OF TRANSACTIONS PER TYPE PER YEAR AFTER ACCOUNTING FOR ELECTRONIC DELIVERY

[in millions]

	Count	Estimated low Savings (\$0.035/unit)	Estimated high savings (\$0.32/unit)
Exchange eligibility and enrollment communications	17.7	Year 1: \$1	Year 1: \$4.
Annual notice of benefits	123	Year 5: \$0	Year 5: \$3.
Explanations of Benefits—hospital admissions	96	Year 1: \$4	Year 1: \$31.
Explanations of Benefits—physician's visits	941	Year 5: \$3	Year 5: \$23.
Medical bills—hospital admissions	11	Year 1: \$3	Year 1: \$24.
Medical bills—physician visits	99	Year 5: \$3	Year 5: \$18.
Pharmacy-related notices	2,900	Year 1: \$30	Year 1: \$238.
		Year 5: \$26	Year 5: \$175.
		Year 1: \$0	Year 1: \$3.
		Year 5: \$0	Year 5: \$2.
		Year 1: \$3	Year 1: \$25.
		Year 5: \$3	Year 5: \$18.
		Year 1: \$91	Year 1: \$733.
		Year 5: \$81	Year 5: \$538.
Total, accounting for electronic communications	4,188	Year 1: \$132	Year 1: \$1,059.
		Year 5: \$117	Year 5: \$777.

The primary estimate of annual savings is approximately \$0.63 billion in Year 1 and \$0.51 billion in Year 5 after accounting for electronic delivery. The Department assumes that the nine other CMS regulations or guidelines requiring taglines will continue to be in effect, and the cost of complying with these CMS requirements would need to be subtracted from the total savings that the 2016 Rule's rescission generates for the healthcare sector as set forth in Table 2. These requirements include (1) Group Health Plans and Health Insurance Issuers requirements;³⁶¹ (2) Navigator requirements;³⁶² (3) Non-Navigator Assistance Personnel requirements;³⁶³ Medicaid requirements;³⁶⁴ Medicaid Managed Care requirements;³⁶⁵ CHIP requirements;³⁶⁶ CHIP Managed Care requirements;³⁶⁷ Hospitals Qualifying for Tax-Exempt Status requirements;³⁶⁸ and Medicare Advantage (Part C) and

Prescription Drug Plans (Part D) requirements.³⁶⁹

Comment: Some commenters indicated that the notice and taglines requirements that the Department proposed for removal led to substantial costs that the Department understated. For example, they contended costs may be higher than the Department estimated in the proposed rule because plans had to revise internal documents, incur significant IT costs, and work with outside vendors to implement the 2016 Rule. Commenters also contended the 2016 Rule resulted in significant annual printing costs.

One commenter calculated that the costs of the mailings related to pharmacy services yielded additional costs of \$1 billion a year. The commenter supported the Proposed Rule's RIA aggregate estimate that the requirement would save plans \$101 to \$928 million a year and provided a specific example in which an affected entity reported incurring \$3.9 million in printing costs and \$4 million in operations costs to send 55.5 million communications.

³⁶⁹ Medicare Marketing Guidelines § 30.5.1, <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html>.

Another company reported almost \$1 million in annual increased expenses on toner, developer, paper, and postage related to notice and taglines requirements. Another commenter stated the costs associated with complying with the 2016 Rule's requirement accounts for 4.5% of one company's budgeted operating income. Some commenters also stated the proposed rule would significantly reduce the administrative burden placed on providers, saying that what constitutes a "significant" communication has been insufficiently clear and has resulted in broad interpretations and providers using the taglines in almost every document.

Some commenters estimated that the dental profession has spent over \$240 million to date on compliance with the 2016 Rule. The commenter noted that the time and cost for dental offices to interpret the regulations, print documents, alter existing publications, and modify websites has been significant. Several dental offices believe repealing the notice and taglines requirements will lead to cost savings and will allow staff to spend time on appropriate patient care and communication instead.

One commenter explained that in its Pennsylvania line of business, it serves

³⁶¹ 45 CFR 147.136(e)(2)(iii) and (e)(3), and § 147.200(a)(5).

³⁶² 45 CFR 155.215(c)(4).

³⁶³ 45 CFR 155.215(c)(4).

³⁶⁴ 42 CFR 435.905(b)(3).

³⁶⁵ 42 CFR 438.10(d)(2) through (3), (d)(5)(i) and (iii), and (j).

³⁶⁶ 42 CFR 457.340(a).

³⁶⁷ 42 CFR 457.1207.

³⁶⁸ 26 CFR 1.501(r) through 1(b)(24)(vi).

800,000 persons and sends them 2-page double-sided notices and taglines 6,205,000 times a year under the 2016 Rule, resulting in \$245,175 in annual mailing costs. The commenter noted it has similar experiences in all of its Medicaid lines of business.

Other commenters suggested the Department overestimated the costs of the 2016 Rule's notice and taglines requirements. One association stated that the Department's estimate in the proposed rule overestimated by failing to account for notices generated by a machine, included in bulk mailings, or facilitated through the use of computers. The commenter also believed that, while electronic delivery would eliminate postage costs, it would not shift the cost of paper and printing to the consumer/beneficiary/patient, stating it is unlikely that a significant percentage of individuals would download and print documents sent to them electronically. Similarly, the commenter contended the Department failed to account for the significant degree to which communications can be provided electronically and the degree to which some entities, such as insurance plans, have already been doing so for years.

Another commenter, however, agreed with OCR's calculation that the notice and taglines requirement has resulted in the inclusion of one to two sheets of paper. Similarly, one commenter stated it implemented multiple versions of the two-page notice and taglines on thousands of documents in its businesses, which consumed significant resources. The commenter noted that the requirements also impacted covered entity partners as well, particularly print vendors.

Some commenters asked the Department to separate out costs for providing notices as distinct from providing taglines, and for posting notices as distinct from mailing them.

Response: The Department appreciates the comments regarding the costs of the 2016 Rule's notice and taglines requirements. The Department agrees with commenters who contend that the requirements imposed significant and costly burdens far beyond the estimates set forth in the 2016 Rule. The Department finalizes this rule in significant part to relieve those burdens.

Some commenters contended the Department's estimates in the proposed rule were understated, and others contended the Department's estimates were overstated. The comments generally provided data from specific entities or circumstances.

The Department's estimate of the average cost of mailings is based on data received from covered entities across the affected industry, and generally takes into account processes and methods used in mailings such as machines, computers, and bulk handling. Although the Department suggested that some patients and beneficiaries might print notices electronically mailed to them, the Department did not factor those potential costs in its estimate. To the extent that commenters contended the Department failed to consider the extent to which notices and taglines are delivered electronically, this is incorrect, as the Department's preliminary estimates included downward adjustments to its estimates based on electronic delivery, and its revised estimates reflect a broader range of potential electronic delivery rates. Moreover, other commenters contend that they continue to experience significant costs based on non-electronic delivery—contending in some cases that the Department's estimates of those costs were understated.

Commenters were correct to identify that some costs, such as revising internal documents, IT costs, and setting up relationships with outside vendors, resulted from the 2016 Rule. The Department does not estimate that this final rule will lead to cost savings with regard to those types of expenses, however, because they are generally sunk costs that covered entities incurred at the time of the 2016 Rule and will not be able to recover as a result of this final rule. This final rule does not prohibit entities from continuing to provide the type and number of notices and taglines required by the 2016 Rule, but gives covered entities the flexibility to not provide them.

The Department declines to accept the suggestion of some commenters that the Department separate out the costs of notices from the costs of taglines. Information from covered entities indicates that notices and taglines are usually provided together, often on overlapping pages. Because this final rule removes both requirements, the Department's estimates are intended to cover the costs of both notices and taglines.

Comment: One commenter stated that the Department improperly relied on healthcare corporations for its fact-finding and analysis in the proposed rule. In particular, conclusions that the repetitive nature of notices and taglines dilute messages, that beneficiaries do not want to receive them, and that there is no evidence that more beneficiaries have sought language assistance because

of the notices, were largely gathered from the covered entities themselves.

Response: The Department relies on its own data, publicly available data, and data submitted by members of the public—including covered entities—to attempt to estimate the impact of its regulations. The Department takes into consideration the sources of the data it considers, and attempts to weigh all such data appropriately based on the information the Department has available to it.

f. Costs Arising From Removal of Notice and Taglines Requirement

Repealing the notice and taglines requirement may impose costs, such as decreasing access to, and utilization of, healthcare for non-English speakers by reducing their awareness of available translation services.

Comment: Some commenters generally supported the Department's assessment that the benefits from the notice and taglines requirements were hard to quantify and likely not significant. A health insurance plan commenter stated that since the implementation of the 2016 Rule, it has not experienced significant changes in its member demographics or languages spoken, and has not seen any notable increases in requests for translation services. One commenter also stated that its pharmacy benefit manager found that since 2017, the volume of valid complaints about discrimination are less than 1% overall and could be better handled by personnel already in place. The commenter stated further that since 2017, it has filled approximately 3.5 billion prescriptions and mailed nearly half a billion beneficiary communications. In this time period, approximately 0.002% (26 of 14,000) of calls made to the discrimination hotline were closely related to a complaint. Several commenters stated they did not see a significant increase in requests after the 2016 Rule required notices and taglines, but instead experienced relatively flat demand.

Some commenters also expressed concerns regarding wastefulness of the notice and taglines. A commenter calculated that it has spent nearly \$16 million since 2017 to accommodate the current requirements and will save at least \$3.5 million annually under the proposed rule. One commenter suggested that an analysis of the impact of the notice and taglines should take into account the content and frequency of the notices, overall consumer health literacy, costs and administrative burdens, and whether notices are truly meaningful to consumers.

Other commenters suggested that the 2016 Rule's notice and taglines requirements likely yielded benefits to intended individuals. A hospital commented that it observed a 10% increase in the volume of interpreter service encounters each year over the last three years. Another commenter stated that it saw a 28% reduction on its per-member per-month claims cost with its Spanish-speaking population. Several commenters from a variety of organizations request an analysis of the impact on those who most use the services affected by the proposed provision (LEP individuals) and on those who provide services to the impacted population. Several organizations, including a State government, also contended that LEP individuals are a significant portion of the population and tend towards poorer health outcomes. They also suggested that removing the notice and taglines requirements may cause such individuals to delay care or not receive care until their medical issues are more severe and costlier to treat, and they urged the Department to estimate such costs.

Another commenter stated that even though HHS justified the proposed rule in part by citing data that over three-quarters of the U.S. population over the age of 18 speak only English at home and are not well served by taglines or notices, the commenter believes that if a quarter of the population does not speak English at home that is an argument against repealing the notice and taglines.

Several commenters suggested repeal of the taglines provisions may negatively impact LEP individuals. One commenter cited a study claiming that health inequities cost the U.S. economy \$309.3 billion a year.

Response: The Department appreciates the comments concerning the effectiveness and benefits of the notice and taglines requirements from the 2016 Rule. As noted in the proposed rule, previously received reports from covered entities are consistent with some public comments suggesting that the 2016 Rule's requirements did not appreciably increase the use of translation services. One such report indicated that utilization of translation services did not appreciably rise after the 2016 Rule's imposition of notice and taglines requirements.³⁷⁰ Although some commenters contended that they experienced an increase in translation services after the 2016 Rule, others

reported a different experience. The Department generally agrees with the latter, and the difference in reports from different commenters and other sources reinforces the Department's view of the difficulty of attempting to calculate the 2016 Rule's benefits to individuals needing translation services. The Department does not believe it has data enabling it to fulfill the request of commenters who urged the Department to calculate the value of such benefits lost as the result of this final rule, as distinct from data that more generally estimate costs resulting from inequality or delay in care.

As noted in the proposed rule, there are other reasons to believe the 2016 Rule's notice and taglines requirements imposed burdens disproportionate to potential benefits for intended beneficiaries. The vast majority of recipients of taglines do not require translation services. For example, according to Census statistics, as of 2015, over three-quarters (79%) of the U.S. population over age five speak only English at home, followed by Spanish (13%).³⁷¹ Although a commenter contends this statistic provides an argument in favor of maintaining multi-language taglines, the Department disagrees regarding a requirement to send such taglines where almost 80% of the recipients likely speak only English at home, and a majority of the remainder spoke English "very well."³⁷² Additionally, of persons selecting a written language preference when registering for coverage on the HealthCare.gov platform for 2017, 90.29% selected English, followed by 8.23% who selected Spanish.³⁷³ These

data indicate that, for the large majority of people who receive them, the required language taglines mailings provide little to no benefit because they are already proficient English speakers with little need for translation services.

Furthermore, the 2016 Rule's requirements added 47 languages to existing language access requirements, but that only increased access to 0.4% of the entire U.S. population. This was after broadly defining "limited English proficiency" to include those who speak English "well" but not "very well."³⁷⁴ The Department's Office for Civil Rights also produced a list of the top 15 languages in each State; however, 26 of the languages on OCR's list are spoken by less than 0.004 percent of the population. As a result, in some States, especially those with sparser populations, the 2016 Rule required health insurance issuers to provide taglines services in languages spoken by very few people in the State. For instance, in Wyoming, issuers needed to provide translation notices in Gujarati and Navajo in every significant communication sent to beneficiaries to account for approximately 40 Gujarati speakers and 39 Navajo speakers; in Montana issuers were required to provide notices to account for approximately 80 speakers of Pennsylvania Dutch; and in Puerto Rico, issuers had to provide taglines notices to account for approximately 22 Korean speakers and 22 French Creole speakers.³⁷⁵

The Department also continues to believe that the notice and taglines required by the 2016 Rule imposed burdens on many recipients and may interfere in their receipt and understanding of important healthcare information. Prior to the proposed rule, the Department received many communications from beneficiaries and advocacy groups complaining about the excessive amount of paperwork they receive. These individuals and groups

³⁷¹ U.S. Census Bureau, *B16007: Age by Language Spoken at Home for the Population 5 Years and Over, 2011–2015 American Community Survey* (American FactFinder) (2017), https://factfinder.census.gov/bkmk/table/1.0/en/ACS/16_5YR/S1601/0100000US. See also Kimberly Proctor, Shondelle M. Wilson-Frederick, et al., *The Limited English Proficient Population: Describing Medicare, Medicaid, and Dual Beneficiaries*, 2.1 Health Equity 87 (May 1, 2018), <http://online.liebertpub.com/doi/10.1089/heq.2017.0036> (identifying Spanish as the language of the largest majority of limited English proficient speakers in Medicaid and Medicare, according to the 2014 American Community Survey).

³⁷² U.S. Census Bureau, *B16007: Age by Language Spoken at Home for the Population 5 Years and Over, 2011–2015 American Community Survey* (American FactFinder) (2017), https://factfinder.census.gov/bkmk/table/1.0/en/ACS/16_5YR/S1601/0100000US.

³⁷³ CMS, *Race, Ethnicity, and Language Preference in the Health Insurance Marketplaces 2017 Open Enrollment Period* (April 2017), <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-Race-Ethnicity-and-Language-Preference-Marketplace.pdf>. States that that do not use the HealthCare.gov platform, such as California and New York, were not included in this report.

³⁷⁴ See HHS OCR, *Frequently Asked Questions to Accompany the Estimates of at Least the Top 15 Languages Spoken by Individuals with Limited English Proficiency under Section 1557 of the Affordable Care Act*, Question 2 (Sept. 1, 2016), <https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/top15-languages/index.html> (using 2013 year estimates). See U.S. Census Bureau, *Language Spoken at Home by Ability to Speak English for the Population 5 Years and Over*, https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_14_5YR_B16001&prodType=table (2016 year estimates).

³⁷⁵ OCR, *Resource for Entities Covered by Section 1557 of the Affordable Care Act, Estimates of at Least the Top 15 Languages Spoken by Individuals with Limited English Proficiency for the 50 States, the District of Columbia, and the U.S. Territories* (Aug. 2016), <https://www.hhs.gov/sites/default/files/resources-for-covered-entities-top-15-languages-list.pdf>.

³⁷⁰ See Aetna (May 1, 2017), available at <https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0005>.

explained that few people read the notice and taglines and most ignore the last pages of lengthy health documents. Additionally, documents that contain a significant number of pages that recipients do not value can often induce annoyance or frustration due to perceived wasting of time, ignorance of the customers' actual needs or language abilities, waste of economic resources, or insensitivity to environmental concerns.

These communications coincide with the views of some commenters and generally support the Department's conclusion that the 2016 Rule has resulted in "cognitive overload," where individuals experience a diminished ability to process information when inundated with duplicative information and paperwork. These frustrations, though difficult to quantify, are reasonable to expect given the large volume of healthcare communications with notice and taglines that most Americans receive. It is also reasonable to expect that repeated mailings of taglines to people who do not want them may negatively impact their likelihood to read truly significant documents from their insurers or doctors, and may negatively impact health outcomes in some cases.

It is also noteworthy that other rules exist to benefit the persons whom the 2016 Rule's notice and taglines requirements intended to assist. Regulations under Section 504 of the Rehabilitation Act generally require the provision of auxiliary aids and services in health programs or activities that receive Federal financial assistance. 45 CFR 84.52(d). Because the notice requirement under the 2016 Rule required frequent mailed notification of the availability of auxiliary aids and services, the Department suggested in the proposed rule that repealing the notice of nondiscrimination requirement may result in additional societal costs, such as decreased utilization of auxiliary aids and services by individuals with disabilities due to their reduced awareness of such services. Some commenters agreed, but they did not suggest any way to reliably calculate such effects, and the Department is not aware of any. This impact may also be limited because the Section 504 regulations already require recipients of Federal financial assistance employing fifteen or more persons to provide notice to participants, beneficiaries, applicants, employees, and other interested persons of the availability of such aids and services. 45 CFR 85.12 and § 84.22(f).

Additionally, some commenters contended that repealing the notices

and taglines may lead to persons not being made aware of their right to file complaints with OCR, and that some of those persons may suffer remediable grievances but will not complain to OCR absent notices informing them of the process. The Department continues, however, to not be aware of a way to quantify those potential effects. In addition, as noted above, the regulations implementing Section 1557's four underlying statutes already contain notice provisions, *see* 45 CFR 80.6 and Appendix to Part 80 (Title VI), § 84.8 (Section 504), § 86.9 (Title IX) and § 91.32 (Age Act), and therefore this potential cost may be minimal.

g. Cost Savings From Changes to Language Access Plan Provisions

Although the 2016 Rule did not require covered entities to develop a language access plan, the Rule stated that the development and implementation of a language access plan is a factor the Director "shall" take into account when evaluating whether an entity is in compliance with Section 1557. 45 CFR 92.201(b)(2). Therefore, the Department anticipated that 50% of covered entities would develop and implement a language access plan following issuance of the 2016 Rule. 81 FR at 31454.

Comment: One commenter noted that physician group practices report financial losses and significant costs when treating patients that require interpretation or translation services. The commenter stated that providing reimbursement at the Federal level would help offset extra costs incurred to provide these services free of charge and reimburse group practices for increased upfront costs and time required to care for LEP individuals. The commenter contended that face-to-face interpretation services cost between \$50 and \$150 per hour and may include a minimum hour requirement and transportation fee. The commenter points to one practice that reported being billed nearly \$300 for a single in-person interpreter service this year due to a minimum rate and transportation fee. The practice reported paying \$1,200 in interpretation fees for one month for nine individuals.

Response: The Department appreciates these comments. With respect to serving LEP patients, this final rule gives more flexibility to covered entities, while specific obligations to patients will be governed by criteria that has been set forth in longstanding guidelines. It is not within the scope of this rule to provide for Federal reimbursements.

Comment: Several commenters claim the proposed rule failed to consider the benefits to LEP individuals that will be lost by repealing certain provisions. Such commenters state there are tens of millions of LEP people who rely on protections from Section 1557. Another commenter notes that four million Medicare beneficiaries are LEP. A commenter notes that only 15 States use the Medicaid option to reimburse for interpretation. Commenters state that the language access protections in the 2016 Rule benefit Latino/a patients, Asian American and AAPI patients, LEP gender-based violence victims, low-income LEP patients, older adults, people with disabilities, and lower-income older adults.

Some commenters contend that the rule will lead to reduced awareness of language services by LEP persons and by the general public about their rights and protections. One commenter stated that if the rule is finalized, organizations like community health centers that are not funded or do not receive reimbursement for language services will face increased burdens when fewer clients will be aware of their language access rights and likely turn to them instead of to covered entities.

Commenters opposing the proposed rule claimed it would lead to inequality and a reduction in the quality of language access available; the avoidance of care, leading to worsened conditions and avoidable higher-cost hospital services; increased costs due to missed appointments, delayed care, and "non-compliant" self-care; increased Emergency Room use; lower preventive care access and use; malpractice costs; avoidable hospital readmissions; higher rates of uninsurance; unnecessary tests and procedures; higher rates of mortality; misunderstood diagnoses and prognoses leading to poor quality of care; and costs due to lower rates of outpatient follow-up, poor medication adherence, and lack of understanding of discharge diagnosis and instructions.

One commenter claimed that HHS's estimate that covered entities would save around \$17.7 million per year by eliminating references to language access plans overlooks larger healthcare savings generated by access to interpretation services. Two commenters point to a 2017 study finding that easily accessible language interpretation services avoided an estimated 119 readmissions that were associated with savings of \$161,404 per month in an academic hospital. Two commenters pointed to a 2010 report finding that at least 35 of 1,373 malpractice claims were linked to inadequate language access.

Another commenter cited a report that found that 2.5% of one malpractice carrier's closed claims involved language issues that cost the carrier over \$5 million in damages, settlements, and legal fees. Costs included damages paid to patients, legal fees, time lost when defending the lawsuit, loss of reputation and patients, fear of possible monetary loss, and stress.

Response: The Department acknowledges the potential of reduced awareness of the availability of language services by LEP individuals by the changes made in this rule, or downstream effects on malpractice claims due to less awareness. As noted above, however, this final rule continues to provide protections for LEP individuals and commits the Department to enforcement of Section 1557. The Department believes, therefore, that the negative effects predicted by some commenters may be mitigated by the continued commitment to enforcement of Section 1557. The data cited by commenters either do not assess the overall impact of the 2016 Rule as compared to a regime with continued enforcement of Section 1557, or address information about broader matters without providing a method for the Department to specifically analyze how this final rule will cause the effects commenters fear may occur. In this respect, the Department believes that malpractice carriers themselves, not Federal civil rights regulators, are best equipped to determine what practices malpractice carriers should require for the sake of reducing their own financial risk.

Therefore, in consideration of the public comments and the Department's analyses, the Department adopts the estimates from the proposed rule concerning changes to language access plan provisions.

In the proposed rule, OCR estimated that the burden for developing a language access plan is approximately three hours of medical and health service manager staff time in the first year, and an average of one hour of medical and health service manager staff time per year to update the plan in subsequent years. Throughout, we assume that the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200 percent of the wage rate. The value of an hour of time for people in this occupation category, after adjusting for overhead and benefits, is therefore estimated to be \$109.36 based on Bureau of Labor

Statistics (BLS) data for 2018.³⁷⁶ These are within the general range provided by some commenters' description of costs they have experienced.

The Department estimated that approximately 269,141 entities could potentially make changes and develop language access plans in response to the 2016 Rule, as part of the requirement to take reasonable steps to provide meaningful communication with LEP individuals (calculated by reducing the 275,002 affected entities by the 5,861 hospitals and nursing care facilities that were already subject to language access plan requirements under Medicare Part A). The Department further assumed that only 50% of the identified entities would actually make changes to implement a language access plan. If the actual compliance rate were higher, the costs would be higher. These assumptions imply that the total cost of developing language access plans will be approximately \$44.1 million (269,141 entities multiplied by 50% of entities multiplied by 3 hours per entity multiplied by \$109.36 per hour) in the first year and approximately \$14.7 million (269,141 entities multiplied by 50% of entities multiplied by 1 hour per entity multiplied by \$109.36 per hour) per year in subsequent years. The Department assumes sunk costs cannot be recovered by this rule, and therefore that initial language access plan development costs attributable to the 2016 Rule cannot be recovered.

By repealing the provision of the 2016 Rule regarding the Language Access Plans, the Department estimates annual savings are \$14.7 million.

h. Cost Savings Attributed to Covered Entities' Handling of Certain Grievances

This final rule repeals the requirement for each covered entity with 15 or more employees to have a compliance coordinator and a written grievance procedure to handle complaints alleging violations of Section 1557. The Department estimates that, under the final rule, covered entities no longer have to incur certain labor costs associated with processing grievances related to sex discrimination complaints as they relate to gender identity as defined under the 2016 Rule because such definitions would be repealed and no longer binding. This repeal would not, however, affect the independent obligations that entities covered by Section 1557 have to comply with Federal regulations under Section 504 and Title IX to have written

processes in place to handle grievances alleging certain disability and sex discrimination claims, respectively.³⁷⁷

For the sake of consistency and convenience, the Department used the methodology from the 2016 Rule as a foundation for estimating the projected savings from this proposed rule provision.

The 2016 Rule estimated that, in years three through five of the 2016 Rule's implementation, covered entities with 15 or more employees would incur \$85.5 million in costs annually to handle Section 1557 grievances. 81 FR at 31458. This estimate assumed that covered entities would experience an average increase in grievances equal to OCR's projected long-term increase in caseload of about 1%. *Id.* The 2016 Rule monetized this 1% increase in caseload as a labor cost equivalent to 1% of the annual median wage for a medical and health service manager (occupation code 11-9111). *Id.* The Department continues to assume that OCR's increase in caseload attributed to the 2016 Rule reasonably informs the increase in grievance processing that covered entities will experience.

Based on OCR's tracking of Section 1557 complaints received from promulgation of the 2016 Rule (May 18, 2016) until present, OCR predicts that its long-term caseload would have increased 5% rather than 1% as originally predicted. Further, OCR believes roughly 60% of this increase (which equals 3% of the overall increase) would have been attributable to discrimination claims based on the 2016 Rule's definition of sex discrimination with respect to gender identity and sex stereotyping. The Department uses the phrase "would have" with regard to OCR's caseload because, as described above, the Department has been preliminarily enjoined on a nationwide basis by a Federal court from enforcing claims based on the 2016 Rule's definition of sex discrimination, and those provisions have now been vacated by the same court.

The 2016 Rule asserted that private parties have the right to challenge a violation of Section 1557 or the 2016 Rule in Federal court, independent of OCR enforcement or involvement. 45 CFR 92.302(d). In the preamble to the 2016 Rule, the Department suggested that the ability for private parties to sue

³⁷⁶ BLS, Occupational Employment and Wages (May 2018), https://www.bls.gov/oes/2018/may/oes_nat.htm.

³⁷⁷ See, e.g., 45 CFR 84.7(a) (HHS regulations implementing Section 504) (requiring a written process to be in place for handling grievances alleging disability discrimination), § 86.8(a) (HHS regulations implementing Title IX) (requiring a written process to be in place for handling grievances alleging sex discrimination).

under the 2016 Rule would result in covered entities bearing increased compliance costs. 81 FR at 31395 (“the presence of a coordinator and grievance procedure enhances the covered entity’s accountability and helps bring concerns to prompt resolution, oftentimes prior to an individual bringing a private right of action.”). The preliminary injunction did not apply to suits filed by private parties. Although the Supreme Court has recognized a private right of action for some civil rights statutes enforced by the Department, under this final rule the Department would no longer assert in the regulatory text or the preamble to the rule that a private right of action exists for parties to sue covered entities for any and all alleged violations. Because the issue of whether a person has a right to sue in Federal court under Section 1557 is one determined by the courts themselves and not by the Department’s regulations, the Department does not estimate that this change will lead to any economic impact.

Although this final rule removes from the 2016 Rule the expansive inclusion of gender identity and sex stereotyping in the definition of sex discrimination, a court has recently vacated the gender identity provisions of the 2016 Rule. Regarding sex stereotyping, to the extent the 2016 Rule used that term to encompass gender identity, the sex stereotyping provision had no real-world effect after the court decision. To the extent sex stereotyping in the 2016 Rule did not encompass gender identity, the Supreme Court already recognized a degree of relevance of sex stereotyping in sex discrimination claims. This is discussed in more detail in the section above on sex-based discrimination. Therefore, the Department does not believe there would be a direct material economic impact regarding grievance procedures from this final rule’s change

in the definitions concerning sex stereotyping.

In addition, due to voluntary policies or more stringent State requirements, the Department expects that 50% of covered entities would likely continue to accept and handle grievances alleging discrimination based on gender identity and sex stereotyping as set forth under the 2016 Rule.

In the proposed rule, the Department estimated that covered entities would have experienced a 3% increase in gender identity and sex stereotyping grievance claims over the long term due to the 2016 Rule, and half of that caseload (1.5%) could have been due to the 2016 Rule’s language encompassing gender identity and sex stereotyping claims in States where covered entities are not otherwise required to handle those claims. The proposed rule estimated an annual savings in labor attributed to a 1.5% decrease in grievance caseload as \$123.4 million, representing 1.5% of the annual median wage of a medical and health service manager (\$199,472 fully loaded) multiplied by the 41,250 covered entities with 15 or more employees.

Nevertheless, in this final rule the Department does not estimate a cost savings concerning grievance procedures. This is because, as stated repeatedly elsewhere, the court order vacating the gender identity provisions of the 2016 Rule means that this final rule’s changes concerning gender identity will have no direct material economic impact. The *Franciscan Alliance* court order forms the new legal baseline in this respect, and therefore the primarily-emphasized economic baseline, for the purposes of this estimate. To the extent sex-stereotyping claims remain viable, they were already authorized by the Supreme Court’s longstanding interpretation of sex stereotyping.

i. Additional Costs for Training and Familiarization

To comply with the final rule, the Department anticipates that some covered entities may incur costs to re-train employees in order to realize potential longer-term costs savings from the deregulatory aspects of this final rule’s changes. The Department assumes that employers are most likely to train employees who interact with the public, and will therefore likely train between 40% and 60% of their employees, as the percentage of employees that interact with patients and the public varies by covered entity. For purposes of the analysis, the Department assumes that 50% of the covered entity’s staff will receive one-time training on the requirements of the regulation. It uses the 50% estimate as a proxy, given the lack of certain information as described below. For the purposes of the analysis, the Department does not distinguish between employees whom covered entities will train and those who obtain training independently of a covered entity.

i. Number of Covered Entities That May Train Workers

The 2016 Rule estimated that 275,002 covered entities would train their employees on the rule’s requirements in general (including training regarding language access provisions), and used that 275,002 figure as the basis for calculating costs to covered entities arising specifically out of the rule’s prohibition on discrimination on the basis of sex. *See* 81 FR at 31450. The Department assumes, for purposes of this analysis, that the 2016 Rule’s estimate was an accurate and reasonable basis for calculating costs arising from the need to provide training regarding the 2016 Rule.

TABLE 3—NUMBER OF HEALTHCARE ENTITY FIRMS COVERED BY RULE

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
621491	HMO medical centers	104
621492	Kidney dialysis centers	492
621493	Freestanding ambulatory surgical and emergency centers	4,121
621498	All other outpatient care centers	5,399
6215	Medical and diagnostic laboratories	7,958
6216	Home healthcare services	21,668
6219	All other ambulatory healthcare services	6,956
62321	Residential intellectual and developmental disability facilities	6,225
6221	General medical and surgical hospitals	2,904
6222	Psychiatric and substance abuse hospitals	411
6223	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing care facilities (skilled nursing facilities)	8,623
44611	Pharmacies and drug stores	18,852
6211	Offices of physicians	185,649
524114	Insurance Issuers	180

TABLE 3—NUMBER OF HEALTHCARE ENTITY FIRMS COVERED BY RULE—Continued

NAIC	Entity type	Number of firms
	Navigator grantees	100
Total Entities	275,002

ii. Number of Individuals Who Will Receive Training

The first category of healthcare staff that may receive training comprises health diagnosing and treating practitioners. This category includes physicians, dentists, optometrists, physician assistants, occupational, physical, speech and other therapists, audiologists, pharmacists, registered nurses, and nurse practitioners. The BLS occupational code for this grouping is 29–1000, and the 2018 reported count for this occupational group is approximately 5.4 million, with average loaded wages of \$98.04 per hour.

The second category of healthcare staff that the Department assumes will receive training comprises degreed technical staff (Occupation code 29–2000) and accounts for 3.1 million workers with average loaded wages of \$46.52 per hour. Technicians work in almost every area of healthcare: x-ray, physical, speech, psychiatric, dietetic, laboratory, nursing, and records technicians, to name but a few areas.

The third category of healthcare staff that the Department assumes will receive training comprises non-degreed medical assistants (Occupation code 31–0000), and includes psychiatric and home health aides, orderlies, dental assistants, and phlebotomists. Healthcare support staffs (technical assistants) operate in the same medical disciplines as technicians, but often lack professional degrees or certificates. The Department refers to this workforce as non-degreed, compared to medical technicians who generally have degrees or certificates. There are approximately 4.1 million individuals employed in these occupations, with average loaded wages of \$31.14 per hour.

The fourth category of healthcare staff that the Department assumes will receive training is healthcare managers (approximately 0.4 million based on BLS data for occupation code 11–9111), with average loaded wages of \$109.36 per hour. Because the Department assesses costs of familiarization with the regulation for one manager at each entity, it assumes that those managers will have already become familiar with the regulation and will not need additional training.

The fifth category of healthcare staff that the Department assumes will receive training is office and administrative assistants—Office and Administrative Support Occupation (Occupation code 43–0000). These workers are often the first staff patients encounter in a health facility and, because of this, covered entities might find it important that staff, such as receptionists and assistants, receive training on the regulatory requirements. Approximately 2.8 million individuals were employed in these occupations in health facilities in 2018, with average loaded wages of \$36.50 per hour. The Department assumes that outreach workers are included in the five categories listed above, especially in the manager category.

iii. Total Costs of Training

The 2016 Rule estimated that covered entities would incur \$420.8 million in undiscounted costs to train employees on the requirements of the Rule, distributed roughly evenly over the first two years after the 2016 Rule’s effective date. 81 FR at 31458. This conclusion presumed covered entities were already periodically training employees on their obligations under Section 1557, but that the 2016 Rule’s new sex discrimination requirements would induce covered entities to engage in additional “comprehensive training.” 81 FR at 31447.

For the purposes of this regulatory impact analysis, the Department assumes covered entities would face similar costs to retrain the workforce on this final rule’s requirements.³⁷⁸ However, because some covered entities will avoid incurring training expenses when they are not required to (as they will not be subject to the final rule), and because several States with large populations already prohibit gender identity discrimination in healthcare, the Department further assumes that only 50% of covered entities would modify their policies and procedures to reflect the changes in the final rule. Moreover, to the extent entities were

³⁷⁸ Training costs in the 2016 Rule relied upon 2014 wages. See, e.g., 81 FR at 31451 (estimating the median hourly wage for occupation code 29–1000 at \$36.26, unloaded, at <https://www.bls.gov/oes/special.requests/oesm14nat.zip>).

motivated to provide training specifically due to the sex discrimination components of the 2016 Rule, a court has already vacated the gender identity and termination of pregnancy provisions of the 2016 Rule, and this final rule simply amends the Code of Federal Regulations to conform to the *vacatur* in that regard. The Department further assumes that 50% of covered entities, or 137,501, would train their employees to reflect the changes in this final rule. As in the 2016 Rule, the Department assumes that approximately half of the employees at these covered entities will engage in an average of an additional hour of training, and that this will occur in the first year of implementing this rule. These assumptions imply total training costs of \$235.9 million. The 2016 Rule’s calculations of training costs did not anticipate any ongoing training costs after year one—either in the form of annual refresher training for returning employees or training for new employees. The Department now believes that covered entities likely incur such costs, but assumes that equal costs would also be incurred under this final rule. Therefore, the Department has excluded ongoing training costs from the calculation of the baseline and from the calculation of the projected costs of the proposed rule, because such training has a net zero effect on projected costs.

j. Additional Costs for Revising Policies and Procedures

As discussed above, the Department anticipates that 50% of covered entities, or approximately 137,501 entities, would choose to revise their policies or procedures to reflect this final rule’s clarification of the application of Section 1557, while other covered entities may retain their policies to ensure compliance with State or local laws. The Department assumes that it would take, on average, three to five hours for a provider to modify policies and procedures concerning this final rule. The Department selects four hours, the midpoint of this range, for the analysis. The Department further assumes that an average of three of these hours would be spent by a mid-level manager equivalent to a first-line

supervisor (Occupation code 43–1011), at a cost of \$57.06 per hour³⁷⁹ after adjusting for overhead and benefits, while an average of one hour would be spent by executive staff equivalent to a general and operations manager (Occupation code 11–1021), at a cost of \$119.12 per hour³⁸⁰ after adjusting for overhead and benefits. The total cost for the estimated 137,501 covered entities to make their policies and procedures consistent with the final rule’s changes is estimated to be approximately \$39.9 million following implementation of this rule.

The above estimates of time and number of entities that would choose to revise their policies under the regulation are approximate estimates based on general BLS data. Due to the wide range of types and sizes of covered entities, from complex multi-divisional hospitals to small neighborhood clinics and physician offices, the above estimates of time and number of entities that would choose to revise their policies under the regulation is difficult to calculate precisely.

k. Other Benefits or Costs

The 2016 Rule’s regulatory impact analysis did not include an economic cost-benefit analysis of the regulation’s impact on health insurance benefit design. The Department lacks sufficient data on how much burden the 2016 Rule has placed on the development and operation of insurance benefits policies, and thus is unable to fully assess the benefit of removing this requirement.

The Department received several comments concerning the impact of the proposed rule on issues concerning discrimination on the basis of LGBTQ status, sex stereotyping, termination of pregnancy, and other provisions.

Comment: Many commenters objected that the Department did not estimate the potential for increases in the denial, delay, or substandard delivery of healthcare services from the rule’s changes concerning gender identity.

One commenter suggested exploring quantitative analysis based on a survey by Harvard University and National Public Radio (NPR) in which 18% of LGBTQ people polled in 2017 reported foregoing care that they need, including preventive care, due to fears of or experiences of discrimination (including 22% of transgender people).³⁸¹ The comment estimated that

this regulation will cost \$1.4 billion in excess costs over the next ten years simply to treat cases of four particular cancers that would have been detected and prevented by screening, and that there will be an 18% increase in preventable mortality from these four cancers among LGBT people. The comment cited the 2016 value of a statistical life (VSL) used by the U.S. Department of Transportation to estimate these preventable deaths as being worth \$39 billion to the U.S. economy over the next ten years.

Another commenter provided a list of potential sources of economic costs the proposed rule could produce concerning transgender patients, including out-of-pocket costs shifted because of transgender exclusions; increased costs from healthcare issues exacerbated by discriminatory delay or denial of care; increased costs related to sex coding; or increased costs due to substandard delivery of care. Other commenters similarly contended that literature on increased costs due to discrimination could be used to estimate economic costs. But such commenters did not provide quantitative values of such costs, or of ways to attribute the costs or portions thereof to this rulemaking.

One healthcare provider stated that they have not incurred any unreasonable costs in delivering care to its LGBTQ patients from complying with nondiscrimination protections based on sexual orientation and gender identity. The commenter added that adopting transgender-inclusive healthcare practices can reduce the costs associated with complications that arise when care is delayed or denied transgender patients due to discrimination.

One commenter stated that patients without primary care would experience an increase in emergency room visits, which would result in increased costs for the healthcare system—including from hospitals’ and the government’s absorbing and subsidizing the costs of uninsured patients.

Commenters raised similar comments concerning sexual orientation as did the commenters discussing gender identity or LGBTQ issues more broadly, contending the proposed rule should estimate the impact of not including protections against sexual orientation discrimination.

Response: The Department appreciates the comments concerning the regulatory impact of this final rule’s changes concerning gender identity.

available at <https://www.npr.org/documents/2017/nov/npr-discrimination-lgbtq-final.pdf>.

This rule commits the Department to vigorous enforcement of the nondiscrimination provisions of Section 1557 and Title IX as incorporated therein, according to the plain meaning of the protections set forth in those statutes. In addition, the gender identity provisions of the 2016 Rule were preliminarily enjoined on a nationwide basis by a court from December 2016 until October 2019, when they were vacated entirely. As a result, this final rule maintains the status quo with respect to gender identity under the enforcement of the Section 1557 rule.

Based on the Department’s review of the public comments, the commenters did not provide, and the Department is not otherwise aware of, reliable data or methods to calculate the economic impacts concerning gender identity that they allege would be attributable to this final rule. Commenters cited various sources of data, but many were either too narrow in not providing a basis to estimate the impacts of this rule nationwide, or were too broad in discussing aspects of the healthcare system but not impacts of this specific rule. For example, citations to data about the percent of transgender persons who forgo care due to fears or experiences of discrimination, and a calculation of the costs to the healthcare system resulting from such occurrences, are not sufficient to estimate the effects of this final rule itself, due to court orders preliminarily enjoining and then vacating provisions in the 2016 Rule, State and local laws that already provide gender identity protections, and other factors that prevent the Department from showing that this final rule is causing those effects. For example, one poll cited by commenters was conducted in 2017, when the 2016 Rule was already in place, but when its gender identity provisions were preliminarily enjoined. So it is not clear from that poll that the 2016 Rule yielded the benefits the commenters say it did, and it is even less clear how this final rule will remove those benefits. Generally, the Department’s review of comments is that concerns about increased costs to LGBT persons from this final rule do not offer sufficient quantitative evidence for the Department to provide an estimate along these dimensions.

Finally, as discussed above, because the 2016 Rule contained no prohibition on sexual orientation discrimination in the 2016 Rule, the Department does not deem there to be an economic impact resulting from this final rule with respect to sexual orientation discrimination.

³⁷⁹ BLS, Occupational Employment and Wages, May 2018, https://www.bls.gov/oes/2018/may/oes_nat.htm.

³⁸⁰ *Id.*

³⁸¹ NPR, “Discrimination in America: Experiences and Views of LGBTQ Americans” (Nov. 2017),

Consequently, commenters' warnings of effects of this rule's changes on these issues do not give rise to impacts that are properly attributable to this rule and that the Department believes can be estimated for the purposes of this analysis.

Comment: One commenter contended that the Department should include analysis of the consequences of removing sex stereotyping language from the rule. The commenter suggested that costs of this rescission could include increased confusion for patients and covered entities, increased discrimination based on sex stereotyping with attendant economic and non-economic costs to patients and the public health system, increased need for legal advice, and increased litigation.

Response: To the extent that sex stereotyping language from the 2016 Rule was interpreted to encompass gender identity, court orders have preliminarily enjoined and now vacated those provisions. Therefore, this final rule does not directly induce changes in this regard. To the extent that sex stereotyping is a recognized category of sex discrimination under longstanding Supreme Court precedent, this final rule commits the Department to continuing to vigorously enforce Title IX through Section 1557, and therefore the Department estimates that this final rule will not have any material effect on the scope of sex stereotyping claims as authorized by Title IX and Section 1557.

Comment: A commenter objected that the proposed rule did not estimate the economic impact of withdrawal of Federal guidance and technical support concerning the 2016 Rule.

Response: All guidance and technical support concerning the 2016 Rule was withdrawn by operation of the preamble to the proposed rule, which itself is a guidance document—not directly by this final rule. The outdated guidance documents are in the process of being removed from the Department's websites. The Department is not aware of any data that would allow it to estimate the effects of changes to its sub-regulatory guidance. To the extent that certain guidance and technical support concerned provisions of the 2016 Rule that were enjoined and vacated, this final rule is not the direct cause of the Department's non-enforcement of those provisions.

Comment: Some commenters contended that the proposed rule would lead to economic burdens concerning termination of pregnancy for women and other patients who are denied access to care. One commenter stated that there is well-documented research

that shows the significant healthcare costs women experience when they face healthcare denials. Another commenter stated that women will suffer negative health effects or death if they are denied services relating to complications from an abortion or a miscarriage. Another commenter stated that there are costs to patients facing discrimination as a result of having a previous termination of pregnancy.

Several commenters contended that the proposed rule would place undue costs and burdens on survivors of sexual and domestic violence. The commenters stated that healthcare programs provide critical and costly care for survivors of domestic violence, sexual assault, and human trafficking. The commenters stated that recent data from the CDC shows that the lifetime per-victim cost of intimate partner violence was \$103,767 for women victims, with 59% going to medical costs, and that more than 550,000 injuries due to intimate partner violence require medical attention each year.

Response: The Department appreciates comments in this regard. This final rule fully commits the Department to enforcement of Section 1557 and Title IX to protect women from discrimination on the basis of sex, including and especially vulnerable populations such as survivors of domestic violence, sexual assault, and human trafficking. As noted above, court orders have already enjoined and now vacated the termination of pregnancy provisions from the 2016 Rule. Therefore, this final rule does not have a direct material economic impact with regard to discrimination on the basis of termination of pregnancy. This final rule further ensures the Department will enforce Section 1557 and Title IX consistent with the statutory provisions of Title IX. The Department lacks data or methods enabling it to provide quantitative estimates of any alleged economic impacts related to termination of pregnancy provisions.

Comment: A commenter contended that the Department should conduct a cost-benefit analysis specifically on the impact of adopting Title IX's religious exemptions, or compliance with RFRA.

Response: The Department disagrees. The Title IX statute already includes certain exemptions concerning religious groups, and RFRA protects certain exercises of religion from substantial burdens. This final rule affirms that the Department will only enforce Section 1557 consistent with the statutory provisions of Title IX and RFRA, and amends the Title IX regulations to explicitly include the provisions of the

Title IX statute concerning religious groups and abortion neutrality. As the Department is already bound by statute to implement Title IX and Section 1557 consistent with those statutes and with RFRA, the Department does not attribute its compliance with those statutes to be attributable to this final rule. Economic impacts due to compliance with Title IX and RFRA would be attributable, not to this final rule, but to those statutes themselves, and are not relevant for this regulatory impact analysis.

Comment: One commenter stated that the Department should estimate the economic impacts of its conforming amendments.

Response: Section 1557 encompasses all the CMS programs addressed by the conforming amendments, so the Department's estimates of impacts of changes to the Section 1557 rule already encompass the impact on entities covered by those rules.

(5) Impact on State, Local, and Tribal Entities Under Executive Orders 12866, 13132, and 13175

a. State and Local Governments

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Executive Order 13132, 64 FR 43255 (Aug. 4, 1999). The Department does not believe that this final rule would (1) impose substantial direct requirements costs on State or local governments; (2) preempt State law; or (3) otherwise have Federalism implications. Section 1557 itself provides that it shall not be construed "to supersede State laws that provide additional protections against discrimination on any basis described in subsection (a) [of Section 1557]." 42 U.S.C. 18116(b).

The final rule maintains the full force of Federal civil rights laws' protections against discrimination, but does not attempt to impose a ceiling on how those protections may be observed by States. State and local jurisdictions would continue to have the flexibility to impose additional civil rights protections.

The Department believes that there would be reduced costs to State and local entities, by repealing wasteful Federal mandates and giving States more flexibility to address the needs of LEP individuals or other regional-specific issues.

The Department believes that the change to its Title IX regulations will

not have a substantial direct effect on the States, on the relationship between the national government and the States, on the distribution of power and responsibilities among the various levels of government, or on tribal self-government or sovereignty. This final rule does not subject Title IX funding recipients to new obligations, but rather implements Title IX according to its statutory text, and relieves potential burdens on the States or tribes that could have resulted from any prior interpretation of Title IX by HHS that was inconsistent with the statute. This final rule allows States and tribes to adopt or continue to provide nondiscrimination protections on the basis of sexual orientation, gender identity, or termination of pregnancy, in State, local, and tribal law. Therefore, the Department has determined that this final rule does not have sufficient Federalism implications to warrant the preparation of a Federalism summary impact statement under Executive Order 13132, and that the rule would not implicate the requirements of Executive Orders 12866 and 13175 with respect to tribes.

Comment: One commenter stated it was inconsistent for the Department to say the 2016 Rule imposed burdens on States but that the proposed rule would not impose new burdens.

Response: The 2016 Rule imposed or may have imposed burdens concerning notices and taglines, as well as gender identity and termination of pregnancy provisions beyond the text of Title IX. This final rule can relieve such burdens without imposing new burdens. To the extent that the gender identity and termination of pregnancy provisions were vacated in October 2019, the Department agrees this final rule does not relieve such burdens, but to the same extent, this final rule does not impose any corresponding burdens.

Comment: A commenter stated that HHS points to no evidence of substantial burdens on States and localities as regards the provision or coverage of medically necessary care related to gender transition.

Response: The Department's conclusion that this final rule does not impose new burdens on States and localities is independent of the Department's suggestion that the 2016 Rule, to the extent it prohibited discrimination on grounds exceeding Title IX and State and local law, also imposed burdens on such States and localities.

Comment: One commenter stated that the proposed rule could impose additional costs on States that adopted policies related to private insurance and

Medicaid based on the 2016 Rule that see an increase in healthcare discrimination complaints in their State-level human rights commissions, as HHS OCR will no longer receive such complaints, and such States may reinstate or maintain exclusions and face costly litigation.

Response: The court orders preliminarily enjoining and eventually vacating the 2016 Rule's gender identity and termination of pregnancy provisions have been in effect since December 2016. States have, therefore, not been bound by those provisions, and this final rule's changes in that regard will not cause States to need to change their policies in that regard. States will also not likely see an increase in complaints at the State level as a result of this rule, because HHS OCR has not been able to enforce those provisions for almost the entire lifespan of the 2016 Rule. Finally, this rule does not require States to reinstate exclusions from coverage, so litigation that States might face as a result of doing so are not directly attributable to this final rule.

b. Tribal Governments

Executive Order 12866 directs that significant regulatory actions avoid undue interference with State, local, or tribal governments, in the exercise of their governmental functions. Executive Order 12866 at § 6(a)(3)(B).³⁸² Executive Order 13175 further directs that Agencies respect Indian tribal self-government and sovereignty, honor tribal treaty and other rights, and strive to meet the responsibilities that arise from the unique legal relationship between the Federal Government and Indian tribal governments. Executive Order 13175 at § 2(a). The Department does not believe that the final rule would implicate the requirements of Executive Orders 12866 and 13175 with respect to tribal sovereignty.

(6) Avoidance of Inconsistent, Incompatible, or Duplicative Regulations

Executive Order 12866 requires the Department to avoid issuing regulations that are inconsistent, incompatible, or duplicative with other regulations that it has issued or that have been issued by other Federal agencies. Executive Order 12866 at § 1(b)(10). Section 1557 itself requires avoidance of duplication by providing that the enforcement mechanisms under specifically identified civil rights laws "shall apply for purposes of violations" of Section

³⁸² As stated in the preceding section, the final rule does not have Federalism implications.

1557. 42 U.S.C. 18116(a).³⁸³ The preamble to the 2016 Rule repeatedly stated that, with the exception of issues concerning notices, sex discrimination, and language access plans, it was merely applying civil rights protections that were already applicable and familiar to covered entities. *See* 81 FR at 31446. ("It is important to recognize that this final rule, except in the area of sex discrimination, applies pre-existing requirements in Federal civil rights laws to various entities, the great majority of which have been covered by these requirements for years."); 81 FR at 31464 ("For the most part, because this regulation is consistent with existing standards applicable to the covered entities, the new burdens created by its issuance are minimal.").

With regard to the current 2016 Rule's notice and taglines requirement, covered entities are already subject to dozens of regulations concerning multi-language taglines or notices concerning an individual's right to have documents translated. For example, CMS imposes taglines requirements on health insurance marketplaces, QHP issuers, group health plans and health insurance issuers, navigators, non-navigator assistance personnel, Medicaid, Medicaid managed care, Children's Health Insurance Program, Medicare Advantage, and Medicare Part D.³⁸⁴

³⁸³ For the applicable enforcement mechanisms, *See* 45 CFR parts 80 and 81 (Title VI), 85 (Section 504), 86 (Title IX), 90 and 91 (Age Act).

³⁸⁴ 45 CFR 147.136(e)(2)(iii) and (e)(3) and § 147.200(a)(5) (requiring group health plans and QHP issuers to post taglines in languages in which 10% of individuals with LEP county-wide are exclusively literate on internal claims and appeals notices, and requiring QHP issuers to post on its Summary of Benefits and Coverage), § 155.215(c)(4) (requiring Navigators and non-Navigator personnel in States with Marketplaces operated by HHS to "[p]rovide oral and written notice to consumers with LEP, in their preferred language, informing them of their right to receive language assistance services and how to obtain them"); 42 CFR 435.905(b)(3) (Medicaid regulations requiring individuals to be "informed of the availability of language services . . . and how to access . . . [them] through providing taglines in non-English languages indicating the availability of language services"); § 438.10(c)(5)(i) through (ii) (Medicaid managed care regulations requiring taglines until July 1, 2017); § 438.10(d)(2) through (3), (d)(5)(i), (d)(5)(iii) and (d)(5)(j) (Medicaid managed care regulations requiring taglines on "all written materials for potential enrollees" in the prevalent non-English languages in the State and requiring notification that "oral interpretation is available for any language and written translation is available in prevalent languages" during the rating period for contracts with managed care entities beginning on or after July 1, 2017); § 457.340(a) (applying certain Medicaid requirements to the Children's Health Insurance Program, including § 435.905(b)(3), which requires individuals to be "informed of the availability of language services . . . and how to access . . . [them] through providing taglines in non-English languages indicating the availability of language services"); 457.1207 (applying certain

Furthermore, a Department of Treasury regulation imposed taglines requirements for hospital organizations to qualify for tax-exempt status.³⁸⁵ Additionally, in 2003, the Department issued guidance under Title VI, setting forth a flexible four-factor framework to assess the necessity and reasonableness for providing written translation for LEP individuals.³⁸⁶ Finally, the ACA itself provides that each summary of benefits and coverage provided by issuers—perhaps the single most important health insurance-related document a person receives—must be “presented in a culturally and linguistically appropriate manner.” 42 U.S.C. 300gg–15(b)(2).

Substantially replacing many provisions of the 2016 Rule, including removing the notice and taglines requirements, would eliminate significant redundancies identified above, while maintaining vigorous enforcement of existing Federal civil rights statutes.

B. Executive Order 13771 on Reducing and Controlling Regulatory Costs

This final rule is deemed an E.O. 13771 deregulatory action. The Department estimates that this final rule would generate \$0.24 billion in net annualized savings at a 7% discount rate (discounted relative to year 2016, over a perpetual time horizon, in 2016 dollars).

Medicaid managed care requirements to Children’s Health Insurance Program managed care, including § 438.10(c)(5)(i)–(ii) until the State fiscal year beginning on or after July, 1, 2018), § 438.10(d)(2)–(3), (d)(5)(i), (iii), (j) (applying certain Medicaid managed care requirements to Children’s Health Insurance Program managed care, in the State fiscal year beginning on or after July, 1, 2018); CMS, 2017 Medicare Marketing Guidelines, § 30.5.1, § 100.2.2, § 8, § 80–8 (Jun. 10, 2016), <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2017MedicareMarketingGuidelines2.pdf> (providing a CMS Multi-Language Insert” for certain Medicare Advantage Plan’s and Medicare Part D Plan Sponsors’ marketing materials meeting the percentage translation threshold in § 422.2264(e) and § 423.2264(e) of Title 42 of the CFR). As discussed in the RIA section, we presume 45 CFR 155.205(c)(2)(iii)(A) (requiring Marketplaces and QHP issuers to post taglines on their websites and documents “critical for obtaining health insurance coverage or access to health care services through a QHP”) and other provisions that depend or refer to 45 CFR part 92 for their tagline requirements will no longer apply under this final rule.

³⁸⁵ See 79 FR 78954 (Dec. 31, 2014) (finalizing rule requiring the plain language summary of the financial assistance policy for hospital organizations to qualify as tax exempt, to indicate, if applicable, whether the summary, the financial assistance policy, and the application for such assistance are available in other languages).

³⁸⁶ Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 FR 47315 (Aug. 8, 2003) (HHS LEP Guidance).

Furthermore, Executive Order 13765 states that “the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [ACA] shall exercise all authority and discretion available to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the [ACA] that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, [or] purchasers of health insurance.” Executive Order 13765, 82 FR 8351, 8351 (Jan. 24, 2017). In implementing Section 1557 of the ACA, the 2016 Rule imposed significant regulatory burdens on covered entities, including States, healthcare providers, and health insurers, without sufficient corresponding benefits for patients or beneficiaries. By proposing to substantially replace the 2016 Rule with a regulation that requires compliance with pre-existing civil rights laws, the Department is acting in accordance with Executive Order 13765 in exercising its authority and discretion to address the fiscal burdens on States, and the regulatory burdens imposed on individuals, families, healthcare providers, health insurers, patients, and recipients of healthcare service. The final rule will particularly reduce the economic burden imposed on healthcare providers and insurers required to provide taglines under the 2016 Rule. Decreasing the burden on these providers and insurers will allow them to pass along some of the cost savings to individuals, families, patients, and beneficiaries of insurance to whom they provide services or coverage. Additionally, eliminating the taglines requirement will alleviate burdens on patients and insurance beneficiaries that neither need nor want to receive repeated taglines mailings.

C. Congressional Review Act

The Congressional Review Act (CRA) defines a “major rule” as “any rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of \$100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the

ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.” 5 U.S.C. 804(2). Based on the analysis of this final rule under Executive Order 12866, this rule is expected to be a major rule for purposes of the CRA because it generates cost savings of over \$100 million. The Department will comply with the CRA’s requirements to inform Congress.

D. Unfunded Mandates Reform Act

This final rule is not subject to the Unfunded Mandates Reform Act because it falls under an exception for regulations that establish or enforce any statutory rights that prohibit discrimination on the basis of race, color, religion, sex, national origin, age, handicap, or disability. 2 U.S.C. 1503(2).

E. Regulatory Flexibility Act and Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking

The Regulatory Flexibility Act (RFA) requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (codified at 5 U.S.C. 601 through 612). The RFA requires an agency to describe the impact of a rulemaking on small entities by providing an initial regulatory flexibility analysis, unless the agency expects that the rule will not have a significant economic impact on a substantial number of small entities, provides a factual basis for this determination, and proposes to certify the statement. 5 U.S.C. 603(a), 605(b). If an agency must provide an initial regulatory flexibility analysis, this analysis must address the consideration of regulatory options that would minimize the economic impact of the rule on small entities. 5 U.S.C. 603(c).

For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. HHS considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue for at least five percent of small entities.

Based on its examination, the Department has concluded that this final rule does not have a significant economic impact on a substantial number of small entities. The preamble to the 2016 Rule discussed the character of small entities impacted by the 2016 Rule in detail. 81 FR at 31463–64. Although this final rule will affect numerous small entities, it does not create new or expanded requirements,

and, for all the reasons stated in the RIA, it will be reducing economic burdens on such entities overall. The changes concerning gender identity and termination of pregnancy, having already been vacated by court order, are not expected to result in any impact. The changes to the Department's Title IX rule would not impose any new substantive obligations on Federal funding recipients and, in fact, would provide regulatory clarity and relief for any small entities previously subject to several of the policies and requirements imposed by the Department. The changes made in conforming amendments overlap those made in the Section 1557 rule and described in the RIA.

To the extent that this final rule imposes economic costs, these are generally limited to entities' voluntary choices to revise their policies and procedures and conduct training, and the Department believes these costs are well below those required to have a significant impact on a substantial number of small entities. In addition, the majority of the costs associated with this final rule are proportional to the size of entities, meaning that even the smallest of the affected entities are unlikely to face a substantial impact.

For these reasons, the Secretary certifies that the final rule will not have a significant impact on a substantial number of small entities.

Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking reinforces the requirements of the RFA and requires the Department to notify the Chief Counsel for Advocacy of the Small Business Administration if the final rule may have a significant economic impact on a substantial number of small entities under the RFA. Executive Order 13272, 67 FR 53461 (Aug. 16, 2002). Because the economic impact of the proposed rule is not significant under the RFA, the Department is not subject to Executive Order 13272's notification requirement.

F. Executive Order 12250 on Leadership and Coordination of Nondiscrimination Laws

Pursuant to Executive Order 12250, the Attorney General has the responsibility to "coordinate the implementation and enforcement by Executive agencies of . . . Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*)" Executive Order 12250 at § 1–2(b), 45 FR 72995 (Nov. 2, 1980). The proposed rule was reviewed and approved by the Attorney General, and this final rule was also reviewed and approved by the Attorney General

in finalizing the proposed rule without change.

G. Paperwork Reduction Act

The Department has determined that this final rule does not impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* Under the rule, OCR will update and revise its burden analysis by removing the burden associated with the posting of a nondiscrimination notice and taglines, development and implementation of a language access plan, and designation of a compliance coordinator and adoption of grievance procedures for covered entities with 15 or more employees. OCR has obtained Paperwork Reduction Act approval for this reporting requirement via an update to HHS Form 690 (Consolidated Civil Rights Assurance Form)³⁸⁷ separate from this rulemaking.

(D) Delegation of Authority

Notice is hereby given that I have delegated to the Director, Office for Civil Rights (OCR), with authority to re-delegate, enforcement and administration of Section 1557 of the Patient Protection and Affordable Care Act [42 U.S.C. 18116]. This delegation includes the authority to develop and direct implementation of the requirements of Section 1557 of the Patient Protection and Affordable Care Act [42 U.S.C. 18116] as applied to the Department and recipients of the Department's funds. This delegation supersedes the delegation of authority under Section 1557 to the Health Resources and Services Administration (HRSA) on April 21, 2016 in 81 FR 25680 (April 29, 2016).

List of Subjects

42 CFR Part 438

Civil rights, Discrimination, Grant programs-health, Individuals with disabilities, Medicaid, National origin, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

42 CFR Part 440

Civil rights, Discrimination, Grant programs-health, Individuals with disabilities, Medicaid, National origin, Nondiscrimination, Sex discrimination.

42 CFR Part 460

Age discrimination, Aged, Civil rights, Discrimination, Health Incorporation by reference, Individuals

³⁸⁷ See HHS OCR, Assurance of Compliance Portal, <https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf>.

with disabilities, Medicare, Medicaid, National origin, Nondiscrimination, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 86

Civil rights, Colleges and universities, Employment, Administrative practice and procedure, Buildings and facilities, Education of individuals with disabilities, Education, Educational facilities, Educational research, Educational study programs, Equal educational opportunity, Equal employment opportunity, Graduate fellowship program, Grant programs—education, Individuals with disabilities, Investigations, Reporting and recordkeeping requirements, Sex discrimination, State agreement program, Student aid, Women.

45 CFR Part 92

Administrative practice and procedure, Age discrimination, Civil rights, Discrimination, Elderly, Healthcare, Health facilities, Health insurance, Health programs or activities, Individuals with disabilities, National origin, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 147

Age discrimination, Civil rights, Discrimination, Healthcare, Health insurance, Individuals with disabilities, National origin, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination, State regulation of health insurance.

45 CFR Part 155

Actuarial value, Administration and calculation of advance payments of the premium tax credit, Administrative practice and procedure, Advance payments of premium tax credit, Age discrimination, Civil rights, Cost-sharing reductions, Discrimination, Healthcare access, Health insurance, Individuals with disabilities, National origin, Nondiscrimination, Plan variations, Reporting and recordkeeping requirements, Sex discrimination, State and local governments.

45 CFR Part 156

Administrative appeals, Administrative practice and procedure, Administration and calculation of advance payments of premium tax credit, Advertising, Advisory Committees, Age discrimination, Brokers, Civil rights, Conflict of interest, Consumer protection, Cost-sharing reductions, Discrimination, Grant programs-health, Grants administration,

Healthcare, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, American Indian/Alaska Natives, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, National origin, Nondiscrimination, Payment and collections reports, Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR parts 438, 440, and 460 and 45 CFR parts 86, 92, 147, 155, and 156 as follows:

Title 42—Public Health

PART 438—MANAGED CARE

- 1. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

- 2. Amend § 438.3 by revising paragraph (d)(4) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(d) * * *

(4) The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, or disability.

* * * * *

- 3. Amend § 438.206 by revising paragraph (c)(2) to read as follows:

§ 438.206 Availability of services.

* * * * *

(c) * * *

(2) *Access and cultural considerations.* Each MCO, PIHP, and PAHP participates in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of sex.

* * * * *

PART 440—SERVICES: GENERAL PROVISIONS

- 4. The authority citation for part 440 continues to read as follows:

Authority: 42 U.S.C. 1302.

- 5. Revise § 440.262 to read as follows:

§ 440.262 Access and cultural conditions.

The State must have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, including those with limited English proficiency, diverse cultural and ethnic backgrounds, disabilities, and regardless of sex. These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meets their unique needs.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

- 6. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l, 1395eee(f), and 1396u–4(f).

- 7. Amend § 460.98 by revising paragraph (b)(3) to read as follows:

§ 460.98 Service delivery.

* * * * *

(b) * * *

(3) The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment.

* * * * *

- 8. Amend § 460.112 by revising paragraph (a) to read as follows:

§ 460.112 Specific rights to which a participant is entitled.

(a) *Respect and nondiscrimination.* Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

(1) To receive comprehensive health care in a safe and clean environment and in an accessible manner.

(2) To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care.

(3) Not to be required to perform services for the PACE organization.

(4) To have reasonable access to a telephone.

(5) To be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or

convenience and not required to treat the participant's medical symptoms.

(6) To be encouraged and assisted to exercise rights as a participant, including the Medicare and Medicaid appeals processes as well as civil and other legal rights.

(7) To be encouraged and assisted to recommend changes in policies and services to PACE staff.

* * * * *

Title 45—Public Welfare

PART 86—NONDISCRIMINATION ON THE BASIS OF SEX IN EDUCATION PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

- 9. The authority citation for part 86 is revised to read as follows:

Authority: 20 U.S.C. 1681 through 1688; Pub. L. 100–259, 102 Stat. 28 (Mar. 22, 1988).

- 10. Amend § 86.2:

■ a. In paragraph (a), by adding “, 1687, 1688” after “1686”; and

■ b. In paragraph (n), by removing the words “United States Commissioner of Education” and adding in their place the words “Secretary of Education”.

- 11. Add § 86.18 to read as follows:

§ 86.18 Amendments to conform to statutory exemptions.

(a) Nothing in this part shall be construed to force or require any individual or hospital or any other institution, program, or activity receiving Federal funds to perform or pay for an abortion.

(b) Nothing in this part shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion. Nothing in the preceding sentence shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion.

(c) This part shall be construed consistently with, as applicable, the First Amendment to the Constitution, Title IX's religious exemptions (20 U.S.C. 1681(a)(3) and 1687(4)), the Religious Freedom Restoration Act (42 U.S.C. 2000b *et seq.*), and provisions related to abortion in the Church Amendments (42 U.S.C. 300a–7), the Coats-Snowe Amendment (42 U.S.C. 238n), section 1303 of the Patient Protection and Affordable Care Act (42 U.S.C. 18023), and appropriation rider provisions relating to abortion, to the extent they remain in effect or applicable, such as the Hyde

Amendment (*e.g.*, Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B, secs. 506–07), the Helms Amendment (*e.g.*, Continuing Appropriations Act, 2019, Pub. L. 116–6, Div. F, Title III), and the Weldon Amendment (*e.g.*, Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B, sec. 507(d)).

- 12. Amend § 86.31 by revising paragraph (b) to read as follows:

§ 86.31 Education programs or activities.

* * * * *

(b) *Specific prohibitions.* Except as provided in this subsection, in providing any aid, benefit, or service to a student, a recipient shall not, on the basis of sex:

- (1) Treat one person differently from another in determining whether such person satisfies any requirement or condition for the provision of such aid, benefit, or service;
- (2) Provide different aid, benefits, or services or provide aid, benefits, or services in a different manner;
- (3) Deny any person any such aid, benefit, or service;
- (4) Subject any person to separate or different rules of behavior, sanctions, or other treatment;
- (5) Apply any rule concerning the domicile or residence of a student or applicant, including eligibility for in-State fees and tuition;
- (6) Aid or perpetuate discrimination against any person by providing significant assistance to any agency, organization, or person which discriminates on the basis of sex in providing any aid, benefit or service to students or employees;

- (7) Otherwise limit any person in the enjoyment of any right, privilege, advantage, or opportunity.

* * * * *

- 13. Revise § 86.71 to read as follows:

§ 86.71 Enforcement procedures.

For the purposes of implementing this Part, the procedural provisions applicable to Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d) are hereby adopted and incorporated herein by reference. These procedures may be found at 45 CFR 80.6 through 80.11 and 45 CFR part 81.

- 14. Revise part 92 to read as follows:

PART 92—NONDISCRIMINATION ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AGE, OR DISABILITY IN HEALTH PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE AND PROGRAMS OR ACTIVITIES ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES UNDER TITLE I OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT OR BY ENTITIES ESTABLISHED UNDER SUCH TITLE

Subpart A—General Provisions

Sec.

- 92.1 Purpose.
- 92.2 Nondiscrimination requirements.
- 92.3 Scope of application.
- 92.4 Assurances.
- 92.5 Enforcement mechanisms.
- 92.6 Relationship to other laws.

Subpart B—Specific Applications to Health Programs or Activities

- 92.101 Meaningful access for individuals with limited English proficiency.
- 92.102 Effective communication for individuals with disabilities.
- 92.103 Accessibility standards for buildings and facilities.
- 92.104 Accessibility of information and communication technology.
- 92.105 Requirement to make reasonable modifications.

Authority: 42 U.S.C. 18116; 5 U.S.C. 301, Pub. L. 100–259, 102 Stat. 28 (Mar. 22 1988); 42 U.S.C. 2000d *et seq.* (Title VI of the Civil Rights Act of 1964, as amended); 29 U.S.C. 794 (Section 504 of the Rehabilitation Act of 1973, as amended); 20 U.S.C. 1681 *et seq.* (Title IX of the Education Amendments of 1972, as amended); 42 U.S.C. 6101 *et seq.*; (Age Discrimination Act of 1975, as amended); *Lau v. Nichols*, 414 U.S. 563 (1974).

Subpart A—General Provisions

§ 92.1 Purpose.

The purpose of this part is to provide for the enforcement of section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18116, prohibiting discrimination under any health program or activity receiving Federal financial assistance, or under any program or activity administered by an Executive agency, or by any entity established, under Title I of such law, on the grounds of race, color, national origin, sex, age, or disability, except as provided in Title I of such law (or any amendment thereto). Section 1557 requires the application of the enforcement mechanisms under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), the Age Discrimination Act of 1975 (42 U.S.C.

6101 *et seq.*), and Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) for purposes of violations of Section 1557 and this part.

§ 92.2 Nondiscrimination requirements.

(a) Except as provided in Title I of the Patient Protection and Affordable Care Act (or any amendment thereto), an individual shall not, on any of the grounds set forth in paragraph (b) of this section, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by the U.S. Department of Health and Human Services; or under any program or activity administered by the Department under such Title; or under any program or activity administered by any entity established under such Title.

(b) The grounds are the grounds prohibited under the following statutes:

- (1) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) (race, color, national origin);
- (2) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) (sex);
- (3) The Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*) (age); or
- (4) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) (disability).

§ 92.3 Scope of application.

(a) Except as otherwise provided in this part, this part applies to

(1) Any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by the Department;

(2) Any program or activity administered by the Department under Title I of the Patient Protection and Affordable Care Act; or

(3) Any program or activity administered by any entity established under such Title.

(b) As used in this part, “health program or activity” encompasses all of the operations of entities principally engaged in the business of providing healthcare that receive Federal financial assistance as described in paragraph (a)(1) of this section. For any entity not principally engaged in the business of providing healthcare, the requirements applicable to a “health program or activity” under this part shall apply to such entity’s operations only to the extent any such operation receives Federal financial assistance as described in paragraph (a)(1) of this section.

(c) For purposes of this part, an entity principally or otherwise engaged in the

business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare.

(d) Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 92.4 Assurances.

(a) *Assurances.* An entity applying for Federal financial assistance to which this part applies shall, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director of the Department's Office for Civil Rights, that the entity's health programs or activities will be operated in compliance with section 1557 and this part. A health insurance issuer seeking certification to participate in an Exchange or a State seeking approval to operate a State Exchange to which section 1557 or this part applies shall, as a condition of certification or approval, submit an assurance, on a form specified by the Director of the Department's Office for Civil Rights, that the health program or activity will be operated in compliance with section 1557 and this part. An applicant or entity may incorporate this assurance by reference in subsequent applications to the Department for Federal financial assistance or requests for certification to participate in an Exchange or approval to operate a State Exchange.

(b) *Duration of obligation.* The duration of the assurances required by this subpart is the same as the duration of the assurances required in the Department's regulations implementing section 504 at 45 CFR 84.5(b).

(c) *Covenants.* When Federal financial assistance is provided in the form of real property or interest, the same conditions apply as those contained in the Department's regulations implementing section 504 at 45 CFR 84.5(c), except that the nondiscrimination obligation applies to discrimination on all bases covered under section 1557 and this part.

§ 92.5 Enforcement mechanisms.

(a) The enforcement mechanisms provided for, and available under, Title VI of the Civil Rights Act of 1964 (42

U.S.C. 2000d *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), or Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), including under the Department's regulations implementing those statutes, shall apply for purposes of violations of § 92.2 of this part.

(b) The Director of the Office for Civil Rights has been delegated the authority to enforce 42 U.S.C. 18116 and this part, which includes the authority to handle complaints, initiate and conduct compliance reviews, conduct investigations, supervise and coordinate compliance within the Department, make enforcement referrals to the Department of Justice, in coordination with the Office of the General Counsel and the relevant component or components of the Department, and take other appropriate remedial action as the Director deems necessary, in coordination with the relevant component or components of the Department, and as allowed by law to overcome the effects of violations of 42 U.S.C. 18116 or of this part.

§ 92.6 Relationship to other laws.

(a) Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals aggrieved under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), or Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), or to supersede State laws that provide additional protections against discrimination on any basis described in § 92.2 of this part.

(b) Insofar as the application of any requirement under this part would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections provided by any of the statutes cited in paragraph (a) of this section or provided by the Architectural Barriers Act of 1968 (42 U.S.C. 4151 *et seq.*); the Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008 (42 U.S.C. 12181 *et seq.*), Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d), the Coats-Snowe Amendment (42 U.S.C. 238n), the Church Amendments (42 U.S.C. 300a-7), the Religious Freedom Restoration Act (42 U.S.C. 2000bb *et seq.*), Section 1553 of the Patient Protection and

Affordable Care Act (42 U.S.C. 18113), Section 1303 of the Patient Protection and Affordable Care Act (42 U.S.C. 18023), the Weldon Amendment (Consolidated Appropriations Act, 2019, Pub. L. 115-245, Div. B sec. 209 and sec. 506(d) (Sept. 28, 2018)), or any related, successor, or similar Federal laws or regulations, such application shall not be imposed or required.

Subpart B—Specific Applications to Health Programs or Activities

§ 92.101 Meaningful access for individuals with limited English proficiency.

(a) Any entity operating or administering a health program or activity subject to this part shall take reasonable steps to ensure meaningful access to such programs or activities by limited English proficient individuals.

(b) *Specific applications*—(1) *Enforcement discretion.* In evaluating whether any entity to which paragraph (a) of this section applies has complied with paragraph (a) of this section, the Director of the Department's Office for Civil Rights may assess how such entity balances the following four factors:

(i) The number or proportion of limited English proficient individuals eligible to be served or likely to be encountered in the eligible service population;

(ii) The frequency with which LEP individuals come in contact with the entity's health program, activity, or service;

(iii) The nature and importance of the entity's health program, activity, or service; and

(iv) The resources available to the entity and costs.

(2) *Language assistance services requirements.* Where paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, requires the provision of language assistance services, such services must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency. Language assistance services may include:

(i) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency; and

(ii) Written translation, performed by a qualified translator, of written content in paper or electronic form into languages other than English.

(3) *Specific requirements for interpreter and translation services.* (i) Where paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, requires the provision of interpreter services, they must be provided by an interpreter who:

(A) Adheres to generally accepted interpreter ethics principles, including client confidentiality;

(B) Has demonstrated proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and

(C) Is able to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

(ii) Where paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, requires the provision of translation services for written content (in paper or electronic form), they must be provided by a translator who:

(A) Adheres to generally accepted translator ethics principles, including client confidentiality;

(B) Has demonstrated proficiency in writing and understanding at least written English and the written language in need of translation; and

(C) Is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

(iii) If remote audio interpreting services are required to comply with paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, the entity to which section 1557 applies (as defined in § 92.3 of this part) shall provide:

(A) Real-time, audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality audio without lags or irregular pauses in communication;

(B) A clear, audible transmission of voices; and

(C) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the remote interpreting services.

(4) *Restricted use of certain persons to interpret or facilitate communication.* If an entity is required by paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of

this section, to provide interpretation services, such entity shall not:

(i) Require an individual with limited English proficiency to provide his or her own interpreter;

(ii) Rely on an adult accompanying an individual with limited English proficiency to interpret or facilitate communication, except

(A) In an emergency involving an imminent threat to the safety or welfare of an individual or the public, where there is no qualified interpreter for the individual with limited English proficiency immediately available; or

(B) Where the individual with limited English proficiency specifically requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances;

(iii) Rely on a minor child to interpret or facilitate communication, except in an emergency involving an imminent threat to the safety or welfare of an individual or the public, where there is no qualified interpreter for the individual with limited English proficiency immediately available; or

(iv) Rely on staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency.

(c) *Acceptance of language assistance services is not required.* Nothing in this section shall be construed to require an individual with limited English proficiency to accept language assistance services.

§ 92.102 Effective communication for individuals with disabilities.

(a) Any entity operating or administering a program or activity under this part shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in such programs or activities, in accordance with the standards found at 28 CFR 35.160 through 35.164. Where the regulatory provisions referenced in this section use the term "public entity," the term "entity" shall apply in its place.

(b) A recipient or State Exchange shall provide appropriate auxiliary aids and services, including interpreters and information in alternate formats, to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

(1) Auxiliary aids and services include:

(i) Interpreters on-site or through video remote interpreting (VRI) services, as defined in 28 CFR 35.104 and 36.303(f); note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunication products and systems, text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible information and communication technology; or other effective methods of making aurally delivered information available to individuals who are deaf or hard of hearing; and

(ii) Readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs; large print materials; accessible information and communication technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision.

(2) When an entity is required to provide an interpreter under paragraph (b) of this section, the interpreting service shall be provided to individuals free of charge and in a timely manner, via a remote interpreting service or an onsite appearance, by an interpreter who

(i) Adheres to generally accepted interpreter ethics principles, including client confidentiality; and

(ii) Is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary, terminology and phraseology.

(3) An interpreter for an individual with a disability for purposes of this section can include, for example, sign language interpreters, oral transliterators (individuals who represent or spell in the characters of another alphabet), and cued language transliterators (individuals who represent or spell by using a small number of handshapes).

(c) Disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment, as defined and construed in the Rehabilitation Act, 29 U.S.C. 705(9)(B), which incorporates the definition of disability in the Americans

with Disabilities Act (ADA), as amended (42 U.S.C. 12102 *et seq.*). Where this part cross-references regulatory provisions that use the term “handicap,” “handicap” means “disability” as defined in this section.

§ 92.103 Accessibility standards for buildings and facilities.

(a) Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange shall comply with the 2010 Standards, if the construction or alteration was commenced after July 18, 2016, except that if a facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange, was not covered by the 2010 Standards prior to July 18, 2016, such facility or part of a facility shall comply with the 2010 Standards if the construction was commenced after January 18, 2018. Departures from particular technical and scoping requirements by the use of other methods are permitted where substantially equivalent or greater access to and usability of the facility is provided. All newly constructed or altered buildings or facilities subject to this section shall comply with the requirements for a “public building or facility” as defined in section 106.5 of the 2010 Standards.

(b) Each facility or part of a facility in which health programs or activities under this part are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange in conformance with the 1991 Standards at appendix D to 28 CFR part 36 or the 2010 Standards shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b) with respect to those facilities, if the construction or alteration was commenced on or before July 18, 2016. Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange in conformance with UFAS shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), if the construction was commenced on or before July 18, 2016 and such facility was not covered by the 1991 Standards or 2010 Standards.

(c) For purposes of this part:

(1) “1991 Standards” refers to the 1991 Americans with Disabilities Act Standards for Accessible Design at appendix D to 28 CFR part 36.

(2) “2010 Standards” refers to the 2010 ADA Standards for Accessible Design, as defined in 28 CFR 35.104.

(3) “UFAS” refers to the Uniform Federal Accessibility Standards as promulgated in 49 FR 31528 (Aug. 7, 1984).

§ 92.104 Accessibility of information and communication technology.

(a) Entities required to comply with § 92.2, unless otherwise exempted by this part, shall ensure that their health programs or activities provided through information and communication technology are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities. When undue financial and administrative burdens or a fundamental alteration exist, the covered entity shall provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration, but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through information and communication technology.

(b) A recipient or State Exchange shall ensure that its health programs or activities provided through websites comply with the requirements of Title II of the Americans with Disabilities Act (42 U.S.C. 12131 through 12165).

(c) For purposes of this part, “information and communication technology” (ICT) means information technology and other equipment, systems, technologies, or processes, for which the principal function is the creation, manipulation, storage, display, receipt, or transmission of electronic data and information, as well as any associated content. Examples of ICT include computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; customer premises equipment; multifunction office machines; software; applications; websites; videos; and, electronic documents.

§ 92.105 Requirement to make reasonable modifications.

Any entity to which section 1557 applies (as defined in § 92.3 of this part) shall make reasonable modifications to its policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can

demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term “reasonable modifications” shall be interpreted in a manner consistent with the term as set forth in the regulation promulgated under Title II of the Americans with Disabilities Act, at 28 CFR 35.130(b)(7).

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 15. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 18021, 18031, 18041, 18044, 18054, 18061, 18063, 18071, and 18082, 26 U.S.C. 36B, 31 U.S.C. 9701.

■ 16. Amend § 147.104 by revising paragraph (e) to read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(e) *Marketing.* A health insurance issuer and its officials, employees, agents and representatives must comply with any applicable State laws and regulations regarding marketing by health insurance issuers and cannot employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual’s race, color, national origin, present or predicted disability, age, sex, expected length of life, degree of medical dependency, quality of life, or other health conditions.

* * * * *

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

Subpart B—General Standards Related to the Establishment of an Exchange

■ 17. The authority citation for part 155 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

■ 18. Amend § 155.120 by revising paragraph (c)(1)(ii) to read as follows:

§ 155.120 Non-interference with Federal law and non-discrimination standards.

* * * * *

(c) * * *

(1) * * *

(ii) Not discriminate based on race, color, national origin, disability, age, or sex.

* * * * *

■ 19. Amend § 155.220 by revising paragraph (j)(2)(i) to read as follows:

§ 155.220 Ability of States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(j) * * *

(2) * * *

(i) Provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or

discriminates based on race, color, national origin, disability, age, or sex;

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 20. The authority citation for part 156 continues to read as follows:

Authority: 5 U.S.C. 552; 42 U.S.C. 300jj–11 and 300jj–14.

■ 21. Amend § 156.200 by revising paragraph (e) to read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(e) *Non-discrimination.* A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex.

* * * * *

■ 22. Amend § 156.1230 by revising paragraph (b)(2) to read as follows:

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

* * * * *

(b) * * *

(2) The QHP issuer must provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, or sex.

Dated: May 20, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–11758 Filed 6–12–20; 4:15 pm]

BILLING CODE 4153–01–P

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-01630 (JEB)

INDEX OF DECLARATIONS IN SUPPORT OF
PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION OR, IN THE
ALTERNATIVE, A STAY PENDING JUDICIAL REVIEW
PURSUANT TO 5 U.S.C. § 705

1. Naseema Shafi, CEO of Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health.
2. Dr. Sarah Henn, Chief Health Officer of Whitman-Walker Health.
3. Dr. Randy Pumphrey, Senior Director of Behavioral Health at Whitman-Walker Health.
4. Bamby Salcedo, President and CEO of the TransLatin@ Coalition.
5. Arianna Inurritegui-Lint, Executive Director of Arianna's Center.
6. Darrel Cummings, Chief of Staff of the Los Angeles LGBT Center.
7. Dr. Robert Bolan, Chief Medical Officer and Director of Clinical Research for the Los Angeles LGBT Center.
8. Dr. Ward Carpenter, Co-Director of Health Services for the Los Angeles LGBT Center.
9. Adrian Shanker, Founder and Executive Director of the Bradbury-Sullivan LGBT Community Center.

10. Hector Vargas, Executive Director of American Association of Physicians for Human Rights d/b/a GLMA: Health Professionals Advancing LGBTQ Equality.

11. Roy Harker, Executive Director of AGLP: The Association of LGBTQ+ Psychiatrists.

12. Dr. Deborah Fabian, Member of GLMA: Health Professionals Advancing LGBTQ Equality.

13. Dr. Randi Ettner.

14. Elena Rose Vera, Executive Director of the Trans Lifeline.

15. Carrie Davis, Chief Community Officer of The Trevor Project.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-1630

DECLARATION OF NASEEMA SHAFI, CEO, WHITMAN-WALKER HEALTH

I, Naseema Shafi, declare as follows:

1. I am the Chief Executive Officer of Whitman-Walker Clinic, Inc., d/b/a Whitman-Walker Health (“Whitman-Walker”). I received a J.D. degree from the University of Maryland School of Law in 2005. I have served at Whitman-Walker for more than thirteen years, first as a Compliance Analyst and Director of Compliance; then as Chief Operating Officer, and subsequently as Deputy Executive Director. I assumed the CEO position in January 2019.

2. I am submitting this Declaration in support of Plaintiffs’ motion for a preliminary injunction to prevent the revised regulation under Section 1557, published by the U.S. Department of Health and Human Services (“HHS”) on June 19, 2020 (the “Revised Rule”), from taking effect.

3. The mission of Whitman-Walker is to offer affirming community-based health and wellness services to all with a special expertise in lesbian, gay, bisexual, transgender, queer and questioning (LGBTQ) and HIV care. We empower all persons to live healthy, love openly, and achieve equality and inclusion.

4. Whitman-Walker was founded in 1973, and legally incorporated in 1978 to respond

to the health care needs of the LGBTQ community. In the early 1980s, we were one of the first nonprofit health clinics in the nation to respond to the HIV/AIDS epidemic. We became a Federally Qualified Health Center Look-Alike in 2007 and received full FQHC status in 2013. Our team provides a range of services, including primary medical care; HIV and lesbian, gay and bisexual (LGB) specialty care; medical, behavioral and care coordination services specific for transgender and gender expansive people;; behavioral-health services; dental services; legal services; insurance-navigation services; community health services that include HIV and STI testing; prevention counseling; women's health services; and youth and family support. These services are provided not only to people that live in Washington, DC, but also to people from neighboring states like Maryland and Virginia, and from across the region, including people from Pennsylvania, West Virginia and Delaware. Without nondiscrimination protections in health care, such as those contained in the 2016 Final Rule, many of these patients are unable to find nondiscriminatory, welcoming and competent care in their own communities.

5. In 2019, Whitman-Walker provided health care services to more than 20,760 individuals.

6. Whitman-Walker's patient population is incredibly diverse and reflects Whitman-Walker's commitment to being a health care home for individuals and families that have experienced stigma and discrimination, or have otherwise encountered challenges in obtaining affordable, high-quality health care. We are nationally known as experts in HIV and Hepatitis C specialty care and in gender-affirming care for transgender and gender expansive persons.

7. In 2019, more than 10% of the health care patients and clients we serve identified as transgender or gender expansive. Almost 45% of health care patients—60% of those who provided information on their sexual orientation—identified as lesbian, gay, bisexual, or otherwise

non-heterosexual. More than 9% of patients we served had limited English proficiency.

8. Whitman-Walker also employs a dynamic and diverse workforce that reflects the diversity of the populations we serve. At the present, we employ over 315 medical and behavioral-health providers and support staff, medical-adherence and insurance-navigation professionals, community health-workers, lawyers and paralegals, researchers, administrators, and professionals working in finance, development, human resources, and external affairs. We have employees of many races, ethnicities, genders, sexual orientations, religious and spiritual traditions, and life experiences. What unites us all is our shared commitment to creating and sustaining a welcoming, inclusive health care home for everyone who seeks our care.

9. Over the years, Whitman-Walker health care providers, lawyers and paralegals have encountered many instances of discrimination against our patients and legal clients by health care providers and staff outside of Whitman-Walker, based on sex assigned at birth, gender identity, transgender status, sexual orientation, HIV status, or actual or perceived ethnicity or immigration status. Our health care providers, lawyers, and other staff also have many years of experience advocating for patients with health insurance plans that discriminate against gender-affirming care, same-sex couples, and patients living with HIV or Hepatitis C who need specialized care. As such, Whitman-Walker was extensively involved in the proceedings that resulted in the rule published by HHS in May 2016 (“2016 Final Rule”), the Request for Information in 2013, and the Notice of Proposed Rulemaking in 2019.

10. Whitman-Walker receives various forms of federal funding from HHS and from institutions affiliated with or funded by HHS, including but not limited to funds under the Public Health Services Act (“PHSA”), direct grants, funding under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, 42 U.S.C. § 300ff et seq. (“Ryan White funding”), funds under

the 340B Drug Discount Program, research grants from the Centers for Disease Control and Prevention and the National Institutes of Health, and Medicaid and Medicare reimbursements. Whitman-Walker also receives funds from the Health Resources and Service Administration (“HRSA”) and is a Federally Qualified Health Center. In 2019, Whitman-Walker’s federally funded research contracts and grants totaled more than \$7 million.

11. As an entity principally engaged in the business of providing health care that receives federal funding from HHS, Whitman-Walker is a “health program or activity” subject to the Revised Rule.

12. By eliminating the regulatory protections and clear guidance provided in the 2016 Final Rule, the Revised Rule presents a grave threat to the health and wellbeing of the patient population that we serve, most specifically LGBTQ patients and patients with LEP. The Revised Rule also frustrates our ability to provide referrals to our patients and imposes increased costs on Whitman-Walker.

Harms to Whitman-Walker’s LGBTQ Patients

13. The Revised Rule eliminates the definition of “on the basis of sex” and the specific prohibition of discrimination on the basis of gender identity, transgender status, and sex stereotyping. The Revised Rule also eliminates specific provisions related to discrimination against transgender individuals, as well as the provision relating to the discrimination on the basis of association. The elimination of these provisions will result in direct harms to the LGBTQ patients that Whitman-Walker serves.

14. The LGBTQ patients and clients Whitman-Walker serves, especially Whitman-Walker’s transgender and gender-expansive patients, already face particularly acute barriers to care and health disparities that will be compounded by the Revised Rule. It is quite likely that the

Revised Rule will result in a substantial increase in discrimination against LGBTQ individuals by health care providers and institutions outside of Whitman-Walker, as well as by health insurance companies.

15. Dr. Henn's and Dr. Pumphrey's declarations describe a number of incidents of discrimination that our patients have encountered in other health care facilities and offices that our patients have reported to our medical and behavioral health providers. In addition, the lawyers, legal assistants and volunteer attorneys in our Legal Services Department have learned of many similar incidents from their clients.

16. Since the mid-1980s, Whitman-Walker has had an in-house Legal Services Department. Our attorneys and legal assistants provide information, counseling, and representation to Whitman-Walker's patients, and to others in the community who are LGBTQ or living with HIV, on a wide range of civil legal matters that relate directly or indirectly to health and wellness – including access to health care and discrimination based on HIV, sexual orientation, or gender identity. They also oversee legal clinics, staffed largely by volunteer attorneys, which assist transgender and gender-nonconforming individuals to change their legal names and to correct their birth certificates, driver's licenses, passports, Social Security records, and other identity documents to reflect their new names and actual gender identities.

17. Over the years, Whitman-Walker Legal Services staff and volunteer attorneys have encountered many instances of discrimination by health care providers and their staff based on the sexual orientation or gender identity of patients. Recent examples include:

- a. As recounted in Dr. Henn's Declaration, Whitman-Walker transgender patients seeking gender affirming surgery have been rejected at local hospitals, even for procedures that are often performed on non-transgender patients (such as breast

surgery), and even though the patients had health insurance or were otherwise able to pay for the procedures.

- b. In one instance, a health care worker at a dialysis clinic confronted a Whitman-Walker patient with end-stage renal disease and objected to being involved in the patient's care because of hostility to his sexual orientation.
- c. In another case, a transgender woman who was about to have surgery at a Washington, DC hospital for an inner ear condition (unrelated in any way to her transgender-related health care) was confronted and harassed by hospital staff objecting to her gender identity. She was repeatedly and intentionally referred to as "he" and as "a man" by staff in the radiology department when she went for a pre-surgical scan; by desk staff at the surgery center; and by the nurse preparing her for surgery. Several nurses talked about her with each other and laughed. One staff person refused to talk with the patient when she addressed them. Even the anesthesiologist who she was expected to entrust with her life in one of her most vulnerable moments before surgery, mocked her and intentionally referred to her as a man. Health care providers are supposed to provide comfort to patients when they seek health care. Instead, the staff increased her fear just before her surgery because they showed complete disrespect and lack of care for the patient's health and wellbeing.
- d. Another transgender woman went to the office of an ophthalmologist at the same medical center for an eye exam. She arrived on time, filled out the initial paperwork, and then waited for about 45 minutes without being called for her appointment. The patient went to the desk to inquire, and was treated rudely by

the staff. The staff then arbitrarily called a security guard to eject her from the office. As the patient spoke to the security guard, one of the clinic staff came to her and said, loudly and offensively, “Sir, your kind needs to go away. We’re not serving your kind.” She complained to the Office of the Chief Medical Officer and was eventually seen by the ophthalmologist on another day, after considerable effort by her and Whitman-Walker staff.

- e. A transgender woman was seen by a medical provider at Whitman-Walker, who examined her and determined she might have broken her ankle. She was sent to the Emergency Room at a Washington, DC hospital. She identified herself to the ER check-in staff as a woman and presented a driver’s license that contained a female gender marker. She then waited for a number of hours (she remembers five or six) without being examined. When she inquired about the delay, she was treated rudely and misgendered by ER staff. She was finally called from the waiting area, but was taken to the men’s dressing room, rather than the area for women patients, to undress and put on a gown for a scan. During the four or more hours before she received the scan, examination and treatment, she suffered very significant physical pain.

18. By eliminating the explicit protections against discrimination based on gender identity, transgender status, and failure to conform with sex stereotypes, the Revised Rule invites an increase in discriminatory experiences for LGBTQ patients seeking health care services, such as those documented above. This result in harm to the patients and community that Whitman-Walker serves.

19. The discriminatory experiences LGBTQ patients have with other health care

providers erode patients' trust in health care providers overall and thus also challenges the ability of Whitman-Walker to treat its patients effectively and provide appropriate services and referrals.

20. The Revised Rule also empowers religiously-motivated discriminatory behavior by health care providers that is corrosive to fundamental professional standards, threatens patients' welfare, and places a significant strain on our ability to fulfill our critical mission. For example, the Revised Rule undermines our ability to provide referrals and our patients' ability to access health care. A significant amount of medical care in the United States is provided by religiously affiliated hospitals. This is illustrated by the fact that more than one in every six hospital beds in the country are in religiously-affiliated hospitals.¹ To the extent that the Revised Rule leads these institutions (or even a fraction of the medical professionals and staff at these institutions) to rely on the Rule's broad religious exemptions and refuse to provide care to LGBTQ patients, many patients will be left without other treatment options and there will be fewer specialists to whom we can refer our patients and feel confident that we are not exposing our patients to religiously-motivated discriminatory behavior.

21. The discrimination invited by the Revised Rule will also encourage LGBTQ patients to remain closeted to the extent possible when seeking medical care outside Whitman-Walker. When patients remain closeted to a health care provider, however, they are exposed to significant adverse health consequences. For instance, a patient who conceals or fails to disclose a same-sex sexual history may not be screened for HIV or other relevant infections or cancers, or may not be prescribed preventative medications such as PrEP, which is extremely effective at preventing HIV transmission. Patients who fail fully to disclose their gender identity and sex

¹ Julia Kaye, et al., Am. Civil Liberties Union, *Health Care Denied: Patients and Physicians Speak Out About Catholic Hospitals and the Threat to Women's Health and Lives* (Mar. 2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

assigned at birth may not undergo medically indicated tests or screenings (such as tests for cervical or breast cancer for some transgender men, or testicular or prostate cancer for some transgender women).

22. Furthermore, at a time of public health crisis such as the present COVID-19 pandemic, the delay of necessary health care for fear of discrimination will make it harder for health care providers to help stem the pandemic, thereby potentially exposing more people to COVID-19, to which LGBTQ people are already more vulnerable.

23. The Revised Rule further notes that covered entities are not discriminating on the basis of sex if they refuse to use a transgender patient's pronouns consistent with their gender identity; refuse them access to sex-specific facilities that are consistent with their gender identity and instead forces them into facilities/shared rooms based on the sex they were incorrectly assigned at birth; and identifies them by the sex they were incorrectly assigned at birth such as on patient identification bracelets and any signage outside the patient's room. These discriminatory actions, which as documented above, have been experienced by Whitman-Walker's patients at other health care facilities, are inconsistent with the 2016 Final Rule and Section 1557 of the Affordable Care Act. They are also detrimental to transgender patients' health and wellbeing, and can lead to significant distress.

24. Whitman-Walker medical and behavioral health providers, care navigators and attorneys assist hundreds of transgender patients every year to navigate private health plans, Medicaid, and Medicare to obtain the gender-affirming services that they need—including a wide range of surgical procedures and hormone therapy. Many private and public plans continue to resist coverage of medically necessary procedures—if not through blanket exclusions of “sex change” or “sex transition” procedures, then through denials of coverage of specific procedures.

25. The 2016 Final Rule, which prohibits “categorical coverage exclusion[s] or limitation[s] for all health services related to gender transition” and denials, limitations, or restrictions “for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual,” 81 Fed. Reg. at 31,472 (formerly codified as 45 C.F.R. § 92.207(b)), has been very valuable in persuading Medicaid administrators, insurance company personnel, and employee health plan sponsors to eliminate outdated exclusions and to agree to cover procedures when supported by evidence of medical necessity.

26. These provisions and others that specify insurance practices and plan features that constitute forms of unlawful discrimination provide useful guidance, not only for consumers and others advocating on their behalf – including health care providers like Whitman-Walker who assist patients in determining coverage of health care being provided or contemplated – but also for health insurance companies and plan administrators. For example, one of our Legal Services attorneys used the 2016 Rule to persuade a client’s union health plan to eliminate a discriminatory exclusion and cover his mastectomy and chest reconstruction. The attorney also relied on the 2016 Rule to successfully overturn a Blue Cross company’s denial of coverage of a transgender client’s breast augmentation and genital surgery.

27. Based on Whitman-Walker’s experience, the Revised Rule, which eliminates the aforementioned provisions, invites health plans to discriminate through the exclusion of gender-affirming procedures, which in turn threatens transgender patients who suffer from crippling gender dysphoria, and through the reinstitution of insurance practices regarding the “tiering” of certain drugs (e.g., to determine co-pays or cost-sharing ratios) that are of great concern to patients living with HIV or other medical conditions or disabilities that require expensive treatments.

28. In addition, the Revised Rule perplexingly exempts many forms of health insurance from Section 1557, subjecting LGBTQ patients who rely on those forms of insurance to discrimination based on sex assigned at birth, gender identity, transgender status, sexual orientation, race, national origin, age, or disability. For example, under the Revised Rule, “an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare.” 85 Fed. Reg. at 37244–45 (to be codified as 45 C.F.R. § 92.3(c)). The Revised Rule also excludes HHS health-related programs and activities from Section 1557, unless the programs were established under Title I of the ACA. This limitation would affect numerous health-related programs and activities, including those of the Centers for Medicare and Medicaid Services. The narrowing of covered entities under Section 1557 will result in discrimination against LGBTQ patients, who already face disproportionate barriers to accessing appropriate care, and eliminate LGBTQ patient’s remedies to address such discrimination.

29. In sum, the Revised Rule will exacerbate the acute health disparities LGBTQ people already face and send the message that discrimination on the basis of gender identity, transgender status, sexual orientation, and failure to conform with sex stereotypes is permissible under federal law, which will increase the number of Whitman-Walker’s LGBTQ patients who will be denied care outside Whitman-Walker.

Harms to Whitman-Walker’s LEP Patients

30. As noted above, Whitman-Walker serves hundreds of LEP patients in any given year. Language access protections for LEP patients are essential to ensuring that LEP patients receive adequate care, understand their rights, and are able to communicate fully and effectively with their health care providers. Whitman-Walker has found the clear guidance provided by the

2016 Final Rule to be helpful in improving the health and wellbeing of our LEP patients as they obtain care at Whitman-Walker and elsewhere.

31. The Revised Rule, however, eliminates the requirement that covered entities take reasonable steps to provide meaningful access to “each individual with LEP eligible to be served or likely to be encountered” and replaces it with a general reference to “LEP individuals.” See, e.g., 85 Fed. Reg. at 37,245. Focusing on LEP individuals in general as opposed to each individual will result in some individuals not receiving the services they need for meaningful access, and thereby result in more acute health problems and outcomes for patients and raises concerns about patient safety.

32. The weakening of protections for LEP individuals will harm Whitman-Walker’s LEP patients who get care elsewhere or are referred to providers outside our organization for specialty care, as they will no longer benefit from the notices, taglines, and additional language access provisions that are critical to ensure meaningful access to care. The Revised Rule will thus diminish or eliminate meaningful access to health care for Whitman-Walker’s LEP patients, who will not be aware of their rights or the programs or services available to them when they go to other health care facilities.

33. Whitman-Walker will face increased burdens due to fewer clients being aware of their language access rights and the likelihood that more people will turn to Whitman-Walker for help in their language, rather than other covered health care providers. Whitman-Walker will also be burdened with increased costs because its patients will come to us sicker as a result of inadequate care elsewhere.

Additional Harms to Whitman-Walker

34. Escalating health care discrimination and fear of such discrimination, resulting

from the Revised Rule, is likely to result in increased demand for Whitman-Walker's health care services, which will present considerable operational and financial challenges. Many of Whitman-Walker's health care services lose money due to low third-party reimbursement rates and indirect cost reimbursement rates in contracts and grants which are substantially less than Whitman-Walker's cost of service. Increased demand for Whitman-Walker's health care services, driven by increased discrimination and fear of discrimination outside of Whitman-Walker, would exacerbate that pressure. We likely will be called upon to see more patients, and that patient care does not financially cover itself. As a result, Whitman-Walker may not be able to meet the increased demand and sustain the additional financial burdens resulting from an increased load of patients who either fear discrimination elsewhere or who were discriminated against or denied services at other institutions.

35. In addition, Whitman-Walker has large numbers of patients who require gender-affirming care, including hormone therapy and affirming, supportive mental health services. To the extent that the Revised Rule results in insurance plans and insurance companies reducing their coverage of such therapies, Whitman-Walker itself – as well as our patients – will be directly harmed by reduced reimbursements. In order to sustain the care that these patients need, we will be forced to turn to other measures, such as increasing charges to the patients themselves, and increasing our reliance on fundraising and grant revenue (which already is stretched thin).

36. The operational and financial pressures we will likely experience due to increased demand for our services as discrimination, and fear of discrimination, mount in the LGBTQ and LEP communities, will come at a time when Whitman-Walker already is struggling with the challenges posed by the COVID-19 pandemic. Since March of this year, many of our services have temporarily closed, and other health care services are being provided entirely through telemedicine

rather than in-person. Telemedicine services are being reimbursed at rates substantially lower than in-person services. The resulting very significant decline in revenues, and the very great operational challenges posed by suspending many services and re-tooling others, are posing challenges unique in Whitman-Walker's history. It will be particularly difficult to respond to increased demand at this already-difficult time.

37. At the same time, given Whitman-Walker's mission to provide health care to marginalized communities, including the LGBTQ community and people living with HIV, Whitman-Walker needs to increase its education programs and community outreach to help those affected by the Revised Rule find the health care services that they need and assist them with their trauma resulting from the Revised Rule. Whitman-Walker needs to continue informing the community about its commitment to serving all patients in a nondiscriminatory and welcoming manner and notifying its patients that the Revised Rule will not change Whitman-Walker's commitment to providing exceptional health care services to all members of the community. Whitman-Walker will continue fighting for its patients' rights, including, for example, advocating on behalf of transgender patients who seek treatment for gender dysphoria, but who are rejected because of their sex assigned at birth and gender identity. As a result of the Revised Rule, Whitman-Walker will also need to devote more resources to working with outside providers and organizations to remind them of the importance of providing health care to all patients on non-discriminatory terms.

38. The Revised Rule also adversely impacts Whitman-Walker by necessitating a diversion and reallocation of resources in order to provide referrals to patients that it does not have the resources to treat either because Whitman-Walker has reached its capacity for new patients (especially in the behavioral-health departments) or because the patient requires treatment in a

specialty that Whitman-Walker does not offer. These types of referrals are routine at Whitman-Walker where its focus is on primary care and HIV-specialty care. The Revised Rule will make it significantly more difficult and resource-intensive for us to locate, monitor, and provide appropriate referrals. With an increase in referral requests as a result of the Revised Rule, Whitman-Walker will need to allocate additional staff time to pre-screen service referrals to ensure that staff are sending patients to LGBTQ-affirming, LEP-welcoming providers and not to providers who themselves or whose staff would cause additional harm to Whitman-Walker patients.

39. The impact on Whitman-Walker and its patients of a broad, legally unsupported expansion of health care providers' refusal rights is also particularly worrisome. Religiously affiliated hospitals and health care systems occupy a large and growing percentage of health care markets, and providing a broad exemption from Section 1557's nondiscrimination provisions will affect Whitman-Walker's ability to make referrals and result in increased expenditures. It will also cause unnecessary confusion.

* * * * *

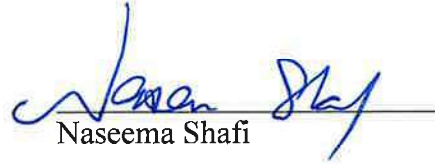
40. Health care systems should be safe places for everyone to seek care; where people's identities are affirmed, regardless of race, religion, sexual orientation, gender identity, disability, national origin, or other characteristics. It is Whitman-Walker's mission to offer affirming community-based health and wellness services to all, with a special expertise in LGBTQ and HIV care, and to empower all persons to live healthy, love openly, and achieve equality and inclusion. The Revised Rule frustrates our ability to live up to our mission by fostering discrimination against Whitman-Walker's LGBTQ patients, LEP patients, and others. The Revised Rule endangers the health, safety, and wellbeing of our patients; inhibits our ability to

provide them with the health care that they need, including the provision of referrals; increases the costs we must incur in order to provide our patients with adequate health care, as well as by the likelihood that more people will turn to Whitman-Walker to fill gaps in care and assistance caused by the Revised Rule; and imposes new compliance costs.

[Signature on next page.]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 1st day of July, 2020.


Naseema Shafi

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-1630

**DECLARATION OF DR. SARAH HENN, MD, MPH
CHIEF HEALTH OFFICER, WHITMAN-WALKER HEALTH**

I, Sarah Henn, declare as follows:

1. I am the Chief Health Officer of Whitman-Walker Clinic, Inc., d/b/a Whitman-Walker Health (“Whitman-Walker”).

2. I received my medical degree from the University of Virginia; interned at Emory University; was a resident in Internal Medicine at the University of Virginia; and completed an Infectious Disease Fellowship at the University of Maryland. I earned a Masters of Public Health degree at The Johns Hopkins Bloomberg School of Public Health. I maintain active board certifications in Infectious Disease and Internal Medicine. A copy of my curriculum vitae is attached as **Exhibit A**.

3. I have been a physician at Whitman-Walker since 2007, and became Chief Health Officer in May 2018. I oversee all health care related services at Whitman-Walker, as well as maintain a panel of patients for whom I provide direct care. In addition, I am the primary investigator for multiple HIV and Hepatitis C treatment and prevention trials, and am the Leader

of our Clinical Research Site for the AIDS Clinical Trials Group funded by the National Institutes of Health.

4. I am submitting this Declaration in support of Plaintiffs' motion for a preliminary injunction to prevent the revised regulation under Section 1557, published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect.

5. Whitman-Walker provides a range of services, including medical and community health care, transgender care and services, behavioral-health services, dental-health services, legal services, insurance-navigation services, and youth and family support. Whitman-Walker provides primary medical care, HIV and Hepatitis C specialty care, and gender-affirming care to transgender and gender non-binary persons within the diverse community of the greater Washington, DC metropolitan area. In calendar year 2019, our medical, dental, behavioral-health and community-health professionals provided health services to 20,760 patients—including medical care to 11,817 individuals, dental care to 2,014 patients, and walk-in sexually-transmitted-infection testing and treatment to 1,762 persons. In 2019, 3,587 of our patients were individuals living with HIV; 2,148 identified as transgender; and 9,295 identified as gay, lesbian, bisexual or otherwise non-heterosexual.

6. Whitman-Walker's patient population, including patients to whom I provide direct care and whose care I oversee, includes many persons who have experienced refusals of health care or who have been subjected to disapproval, disrespect, or hostility from medical providers and staff in hospitals, medical clinics, doctor's offices, or Emergency Medical Services personnel because of their actual or perceived sexual orientation, gender identity, transgender status, gender presentation, ethnicity or race, religious affiliation, poverty, substance use history, or for other reasons.

7. My patients and those whose care I oversee tell us that they are apprehensive or fearful of encountering stigma and discrimination in health care settings because of their past experiences. Many of our patients have delayed medical visits or postponed recommended screenings or treatment because of such fears. Frequently, persons living with HIV, diagnosed with sexually transmitted infections, struggling with substance use disorders, or whose gender identity is different from the sex that they were assigned at birth, face heightened stigma and discrimination and are particularly apprehensive in medical encounters. Our patients' concerns have been magnified by their belief that the federal government is permitting, if not encouraging, discrimination by health care personnel and health care institutions under the Revised Rule.

8. There is every reason to believe that the Revised Rule's elimination of protections from discrimination based on gender identity, sexual orientation, transgender status, failure to conform with sex stereotypes, along with its expansion of religious exemptions and weakening of safeguards for services to patients with Limited English Proficiency (LEP), will result in more discrimination against lesbian, gay, bisexual, transgender, queer and questioning (LGBTQ) patients, and inadequate services to LEP patients, at other clinics, doctors' offices, hospitals, pharmacies, and other health care facilities outside Whitman-Walker.

9. I and other Whitman-Walker health care providers, including referral coordinators, behavioral-health providers, and other staff, have learned of many instances of discrimination, from our patients and from communications with outside providers and staff. Examples include the following:

- a. Whitman-Walker was recently contacted by a transgender woman suffering from tonsillitis. She wanted treatment but knew of no hospital or facility other than Whitman-Walker where she could go. The caller reported that

in her suburban area, she and other transgender individuals she knows are routinely disrespected and poorly treated when they seek medical care, and asked for advice on where transgender patients can receive good care.

- b. A gay man reported that he consulted a cardiologist for a heart issue. The cardiologist reviewed his medications and saw that one was Truvada—an antiretroviral medication that is used for “Pre-Exposure Prophylaxis” or “PrEP”—taken by persons who are not HIV-infected to avoid contracting HIV during sex. The cardiologist was startled and disapproving, and began lecturing the patient about what the cardiologist considered his inappropriate sex life.
- c. A transgender man, together with his girlfriend, consulted a fertility clinic about their pregnancy options. Clinic staff told them that they would not help people like them.
- d. A transgender patient of Whitman-Walker attempted to fill a prescription at a non-Whitman-Walker pharmacy for a hormone prescribed to assist in their gender transition, and was refused by the pharmacist.
- e. Our patients seeking to fill prescriptions for Truvada for PrEP have also been refused by some pharmacies.
- f. A gay man who is a long-term HIV survivor went to a local hospital emergency room after an accident that occurred during sex. He was treated with contempt by ER staff and was lectured about his sex life.
- g. A transgender individual went to a local hospital emergency room suffering from acute abdominal pain. The individual was subjected to intrusive,

hostile questioning by ER personnel, loudly and in public, about their anatomy and gender identity.

- h. One of our physicians, while in residency at a hospital in a major Midwestern city, heard other residents refuse to refer to transgender patients by pronouns conforming to their gender identity, citing their religious beliefs. They continued to refuse even when informed that they were violating hospital policy.
- i. A transgender woman was scheduled to receive an ultrasound for cancer. The first radiological technician she encountered refused to perform the ultrasound. When she protested, a second technician performed the procedure, but mocked her openly.
- j. Transgender patients have reported to us that they have been in medical or mental-health crisis and called for an ambulance, and that the Emergency Medical Service personnel who have arrived on the scene have intentionally used pronouns inconsistent with their gender identity, even when the patients have asked them to stop and told them that their language was increasing their distress.
- k. A gay man who was engaged in sex, while under the influence of drugs, experienced a physical episode and was fearful he was having a heart attack. He called an ambulance, but the Emergency Medical Service personnel who arrived belittled him and his situation and refused to take him to an emergency room.

- l. Local hospitals and surgeons have refused to perform gender-transition-related surgeries on Whitman-Walker transgender patients, even when they routinely perform the procedures in question on non-transgender patients, including in situations where the patient's insurance would cover the procedure or when the patient was able to pay for the procedure. This has happened with orchiectomies, breast augmentations, and breast reductions - procedures which are all routinely performed for treatment of cancer or for other reasons not related to gender identity.
- m. A number of primary care physicians in our area have refused to prescribe hormone therapy for transgender patients seeking to transition from the sex they were assigned at birth to their actual gender identity. Many of these doctors have stated that they are not "comfortable" with such hormone therapy.
- n. Our providers have seen situations in which a teenager who is transgender or gender-expansive has presented at a local hospital with symptoms for which hospitalization was indicated, but their hospitalization was delayed and even denied because hospital personnel took them less seriously than they took other young people with similar presentations who were not transgender.
- o. Our transgender patients frequently report instances of being treated with disrespect and hostility by staff in doctors' offices, hospitals, and clinics. Frequently, staff at these facilities will refuse to address patients by their chosen names and gender pronouns, if these are not the same as the patients'

legal names and sex assigned at birth, or if patients appear to be transgender.

The persistent use of names and pronouns other than what the patients have requested appears intentional and intended to communicate strong disapproval of the patients. I and my staff who frequently consult with transgender patients hear of such experiences from as many as four out of every five transgender patients. To state the obvious, there is no medically indicated reason to refuse to call patients by their names and pronouns, consistent with their gender identities.

10. These and many other experiences reveal that many medical providers and other staff continue to harbor explicit or implicit biases against LGBTQ people. Many providers and staff who harbor such feelings or beliefs nonetheless have provided care to LGBTQ patients, and kept their personal beliefs in check, because of anti-discrimination laws and regulations, such as the 2016 Final Rule; non-discrimination policies at many hospitals, clinics, and other health care facilities; and professional norms. The Revised Rule counteracts such non-discrimination policies and norms by signaling that discrimination based on sexual orientation, gender identity, and transgender status is permissible under federal law, and by extending religious exemptions to health care settings where they are inappropriate and dangerous. The result will likely be a significant increase in discriminatory incidents, denials of care, and the attendant harms to patients' health and well-being.

11. Discriminatory incidents are not only insulting and demoralizing for patients, but can jeopardize the patient's health, when a screening or treatment is denied or postponed, or the patient is discouraged from seeking medical care out of fear of repeated discrimination. Many if not most of my and Whitman-Walker's transgender patients express strong distrust of the health care system

generally, and a demonstrative reluctance to seek care outside Whitman-Walker unless they are in a crisis or in physical or mental stress. This is because they want to avoid discrimination or belittlement. Such incentives to avoid regular check-ups and other medical care can result in disease processes that are more advanced at diagnosis, less responsive to treatment, or even no longer curable in the case of some cancers.

12. In addition, LGBTQ people are more vulnerable to COVID-19. For example, LGBTQ people are less likely compared to the general population to have health insurance to begin with and are more likely to be smokers with the resultant comorbidities such as asthma, COPD, and CVD which increase the risk for complications from COVID-19. LGBTQ people are also more likely to work in jobs in that have been highly affected by the COVID-19 pandemic, often with more exposure and/or higher economic sensitivity to the COVID-19 crisis.¹

13. As health care has had to go virtual due to the COVID-19 pandemic, hard coding within electronic health records and other limitations in functionality have made it very challenging for people with LEP to access care. In many cases for walk-in COVID-19 testing, registration and screening is being accomplished via the telephone. Many LGBTQ people and people with LEP have a challenging time with this need for electronic resources.

14. The Revised Rule frustrates my ability and the ability of my colleagues to successfully refer patients for specialty care from outside providers because we cannot assure our patients that those providers will provide care free from discrimination.

¹ Human Rights Campaign Found., *The Lives and Livelihoods of Many in the L T Community are at Risk Amidst COVID-19 Crisis* (Mar. 2020), https://assets2.hrc.org/files/assets/resources/COVID19-IssueBrief-032020-FINAL.pdf?_ga=2.249711620.386339034.1593392090-1365884386.1591027992.

15. The Revised Rule also erodes trust between patients and their health care providers, endangers the provider-patient relationship, and is likely to harm many patients' health.

16. Good medical care is based on trust as well as frank, and full communication between the patient and their provider. In many, if not most encounters, providers need patients to fully disclose all aspects of their health history, sexual history, substance-use history, lifestyle, and gender identity in order to provide appropriate care for the patients' mental and physical health. Incomplete communication, or miscommunication, can have dangerous consequences. For instance, a patient who conceals or fails to disclose a same-sex sexual history may not be screened for HIV or other relevant infections or cancers; and a patient who fails to fully disclose their gender identity and sex assigned at birth may not undergo medically-indicated tests or screenings (such as tests for cervical or breast cancer for some transgender men, or testicular or prostate cancer for some transgender women). The Revised Rule completely overlooks the importance of this information to medical providers, and instead focuses myopically on the limited instances in which sex assigned at birth may be relevant to care. Patients need to be encouraged to fully disclose all information relevant to their health care and potential treatment, which can only be achieved when patients are assured that the information they provide will be treated confidentially and with respect, and will not be used against them to deny treatment.

17. In order for Whitman-Walker's health care providers to provide proper medical care and services to the LGBTQ community, our health care providers rely on frank and complete communication with their patients and the individuals who seek their services, and want the same happen when our patients need care elsewhere. Without full disclosure, we are not able to treat adequately our patients.

18. Patients remaining closeted to health care providers also results in increased costs to the health care system. When a patient is closeted and medical providers do not order medically necessary tests or screenings as a result, Whitman-Walker and its patients, as well as the health care system as a whole, suffer downstream effects, such as the exacerbation of a patient's distress and more acute conditions, and increased costs. In addition, I and other Whitman-Walker health care providers will bear an increased risk of malpractice when patients do not feel comfortable revealing important information about their sexual orientation, gender identity, and health history.

19. The Revised Rule also discourages LGBTQ patients from seeking preventative screenings and necessary medical treatment for fear of being subjected to discrimination.

20. The delay of preventative screenings and necessary health care can result in more acute health problems and outcomes for patients and raises concerns about patient safety. For example, research has identified pervasive health disparities for LGBTQ people with respect to cancer, HIV, obesity, mental health, tobacco use, and more. The delay of preventative screenings and necessary health care thus endangers the health and wellbeing of Whitman-Walker's LGBTQ patients and exposes them to lasting harms.

21. The delay of preventative screenings and necessary health care at other health care facilities fostered by the Revised Rule will cause LGBTQ patients to come to Whitman-Walker with more acute conditions and/or diseases that are more advanced at diagnosis, less responsive to treatment, or no longer treatable. This will in turn strain Whitman-Walker's resources, increase costs for providers, make it harder for our health care providers to treat the patients, and increase costs to the health care system in general.

22. Discrimination by health insurance providers against transgender individuals is yet another barrier to care that my patients and the patients whose care I oversee frequently experience.

Our providers, care navigators, and Legal Services attorneys continuously advocate for patients whose insurance – including Medicaid plans, Medicare, and private insurance plans – denies coverage of surgical procedures hormone therapies that are medically indicated and vital to patient health and well-being. The 2016 Final Rule has been an important tool in advocating for our patients. By declaring that discrimination in insurance based on gender identity or transgender status is not prohibited in federal law, and by limiting the types of insurance plans that are subject to federal nondiscrimination requirements, the Revised Rule will increase barriers to life-saving, medically-necessary care for transgender patients by allowing health insurers to revert back to policies excluding coverage for gender-affirming care. If patients with such coverage exclusions are to access the care they require, they will incur debilitating out of pocket costs to pay for their medical treatment. For many if not most of our transgender patients, lack of insurance coverage of gender-affirming surgeries and other treatments will mean that they are simply unavailable.

23. Ensuring that our health services are fully accessible to persons with limited English proficiency, and that our health care providers and other staff are able to communicate fully with all of our patients, is critical to Whitman-Walker's mission. Whitman-Walker has a number of patients whose primary language is Spanish or some other language, and who lack English proficiency. In 2019, approximately 9% of our patients had limited proficiency in English and needed interpreter services. Over the past several years, we have devoted considerable time and attention to developing and implementing a language access plan and training all staff in the details of that plan.

24. I and the providers I supervise have patients who, in hospital and medical-clinic settings, were refused Spanish-language interpreters, even when such interpreters were available

in the facility, because the provider or other staff thought that the patient ought to know English, or because of bias against immigrants.

25. Patients in these situations have had difficulty understanding their diagnosis and/or treatment plan, greatly increasing risk of a negative result and harm. Notices to LEP patients explaining their rights and what programs and services are available to them are crucial to promoting positive patient health outcomes. The Revised Rule's elimination of the requirement of such notices will result in harm to Whitman-Walker LEP patients by diminishing their meaningful access to health care, outside of what Whitman-Walker can provide. In addition, the Revised Rule will cause more patients to seek out care at Whitman-Walker due to a lack of appropriate language services available elsewhere.

26. Whitman-Walker's mission and fundamental principles of medical ethics that I adhere to in overseeing and providing care to patients dictate that all patients are deserving of the best and most respectful care available to them. All health care professionals are taught that their personal beliefs about a patient's actions, identity or beliefs cannot compromise the care that they provide to that patient in any way. Whitman-Walker and I, in my role as Chief Health Officer for Whitman-Walker, communicate that message to all health care staff from the beginning of the recruitment process to the first day of employment, and reinforce the message regularly.

27. The possibility that providers outside Whitman-Walker could invoke the overly broad religious exemptions in the Revised Rule to opt out of any aspect of care would fundamentally disrupt our care model and operations, as it would make it harder to refer patients to specialists and strain Whitman-Walker's already limited resources. Such discrimination would also violate basic tenets of medical ethics. Broad-based denials of care cannot be accommodated without lasting damage to the patient morale, health center, and our reputation in the community.

28. The Revised Rule removes or substantially weakens safeguards against health care discrimination against LGBTQ individuals, and the weakening of safeguards for LEP patients will make health care for significant numbers of Latinx people less accessible and less effective. In other words, the Revised Rule will make it harder for us to care for our patients who will face discrimination or have diminished access to care elsewhere as a result of the Revised Rule.

29. Although Whitman-Walker prides itself on being a refuge for LGBTQ individuals, LEP persons, and others who have experienced discrimination or culturally inadequate care elsewhere, it would be quite difficult for us to accommodate the substantial increase in demand for our services caused by the Revised Rule. Many if not most of our services are under-compensated due to private and public insurance reimbursement rates, and grant funds that do not fully account for the actual cost of service. Moreover, the COVID-19 pandemic has posed extraordinary financial and operational challenges. Many of our health services have been temporarily suspended since March of this year, or shifted entirely to telemedicine, with substantially lower reimbursement rates. The logistical challenges remain daunting, even without a significant increase in new patients.

[Signature on next page.]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 30 day of June, 2020.


Sarah Henn, MD, MPH

EXHIBIT A

Curriculum Vitae of Sarah Henn, MD, MPH

Sarah L. Henn, MD, MPH



1525 14th Street NW • Washington, DC 20005 • Phone: 202.745.6174 • E-Mail: shenn@whitman-walker.org

Education and Post-Doctoral Training

Bachelor of Arts	1988 - 1992
Hamilton College, Clinton, New York, Major International and Comparative Political Studies, Minor German	
Doctor of Medicine	1993 - 1997
University of Virginia School of Medicine, Charlottesville, Virginia	
Internship	1997 - 1998
Internal Medicine, Emory University Medical Center, Atlanta, Georgia	
Residency	1998 - 2000
Internal Medicine, University of Virginia Medical Center, Charlottesville, Virginia	
Master of Public Health	2001 - 2003
The Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, Concentration in International Health	
Fellowship	2004 - 2006
Infectious Diseases, University of Maryland Medical Center and the Institute for Human Virology, Baltimore, Maryland	

Certifications, Licensures, & Appointments:

Board Certifications:

- American Board of Internal Medicine, Internal Medicine, 2000, recertified 2010
- American Board of Internal Medicine, Infectious Diseases, 2006, recertified 2016

Medical Licensure:

- District of Columbia, 2007 – present

Academic Appointments:

- George Washington University, Clinical Assistant Professor, 2008 - present

Professional Experience

Chief Health Officer **May 2018 – present**
Whitman-Walker Health, Washington DC

Responsibilities: Medical lead of a Federally Qualified Health Center serving over 12,000 clients with over 300 employees and an annual budget of over 100 million dollars. Key member of the executive team responsible for strategic planning and the overall management of the organization. Reports directly to the CEO/Executive Director.

Key Achievements:

- Established in conjunction with seven regional FQHC leaders the Coordinated Care Network, an incorporated independent entity, in the District of Columbia to centralize coordinated primary care, increase quality, reduce cost, and increase influence with payers and stakeholders positioning WWH effectively for value based payment transformation which negotiates directly with Medicaid MCO payers around service delivery for the care of over 100,000 individuals in the District of Columbia
- Expanded clinical services to include adolescents with a specialty focus on HIV Prevention, Sexual Health, and Gender Affirming Care
- Clinical Research Site (CRS) Leader of AIDS Clinical Trials Group (ACTG) site as part of Johns Hopkins' Clinical Trials Unit (CTU)



- Serves of the Executive Committee of the DC Center for AIDS Research (CFAR) and is a member of the DC CFAR housed at the George Washington University Milken School of Public Health

Senior Director of Health Care Operations and Medical Services

January 2015 – April 2018

Whitman-Walker Health, Washington DC

Responsibilities: Leads medical operations of a Federally Qualified Health Center serving over 18,000 clients with near 300 employees and an annual budget of over 100 million dollars. Serves on the senior leadership team providing strategic direction for the health center. Oversees the integrated delivery of primary medical, specialty HIV, HIV prevention, gender affirming, dental, occupational therapy, aesthetics, laboratory, and pharmacy services. Negotiates and oversees contracts with outside vendors.

Key Achievements:

- Achieved Patient Center Medical Home highest level 3 accreditation for demonstrating strong performance and significant improvement in performance measures across the triple aim of better patient experience, better health, and lower per capita cost.
- Led the design and implementation of an improved patient scheduling system increasing same day and next day scheduled appointments to 30% of all patient visits and decreasing new patient wait times to under one week
- Improved laboratory patient experience while simultaneously negotiating improved rates with LabCorp achieving cost savings of up to 50% on frequently order tests and \$10,000 per month in credit to WWH's account for labs performed for clients who are <200% federal poverty level
- Oversee pharmacy contract and performance in a pharmacy that dispenses up to 1000 prescriptions daily with a net profit of close to a million dollars monthly in close conjunction with the Deputy Executive Director
- Awarded over 1 million dollars in new research grants in 2017 from the National Institute of Drug Abuse and the Patient Centered Outcomes Research Institute
- Significantly improved health center policies, trainings, and practices related to LGBT health helping to result in WWH being recognized as a "Leader in LGBT Healthcare Equity" with a score of 100/100
- Achieved increased service integration and productivity by leading weekly interdepartmental medical operations meetings and working closely with providers to create buy-in and improve morale
- Transitioned medical operations of the Elizabeth Taylor Medical Center serving more than 10,000 patients to a new facility at 1525 14th St NW in May 2015
- Expanded medical services at the Max Robinson Center, in Southeast DC, more than tripling the number of care providers ensuring that the full suite of patient services are consistently available

Interim Sr. Director of Evidence Based Medicine

2015

Whitman-Walker Health, Washington DC

Responsibilities: Oversaw the clinical research department and the execution of large-scale research studies and collaborations. Acted as leader of clinical research site (CRS) for AIDS Clinical Trials Group (ACTG) and primary investigator for the Study to Help the AIDS Research Effort (SHARE), which is one of the four clinical sites for the Multicenter AIDS Cohort Study (MACS).

Key Accomplishments:



- Reorganized the structure of the department to allow for increased staff development opportunities and quality monitoring of research programs
- Maintained industry research funding of over 2 million annually while more than doubling ACTG study participation

Medical Director

2009 – 2014

The Elizabeth Taylor Center, Whitman-Walker Health, Washington DC

Responsibilities: Performed overall planning, organizing, scheduling, directing, and evaluation of clinical medical providers ensuring excellent patient care experience. Worked closely with the Chief Medical Officer and the Senior Director of Quality Improvement in the delivery of the highest quality of care and the development of quality improvement projects.

Key Accomplishments:

- Implemented ongoing provider education to improve quality indicators.
- Supervised 15 providers, including other physicians, physician volunteers, physician-assistants, and nurse practitioners

Staff Physician

2007 - 2009

Whitman-Walker Health, Washington DC

- Provided primary care at clinical sites in Northwest and Southeast Washington, DC and Northern Virginia
- Specialized in complex HIV care and Hepatitis C treatment
- Initiated Hepatitis C treatment program

Clinical Instructor, Division of Infectious Diseases

2006 - 2007

University of Maryland Medical Center, Baltimore, Maryland

- Maintained active outpatient infectious disease clinics at both the University of Maryland and the Veterans Administration Hospital in Baltimore, MD
- Attended on the inpatient HIV hospital services overseeing Infectious Disease fellows, Medical residents, and students
- Developed a research protocol to reduce maternal to child transmission of Hepatitis B in HIV co-infected mothers

Technical Advisor for PEPFAR

2004 - 2007

Institute for Human Virology, Baltimore, Maryland

- Launched and evaluated points of service for HIV/AIDS care in Nigeria
- Provided technical assistance and expertise to Nigerian physicians and medical staff in order to initiate HIV treatment for patients

Clinical Associate Staff Physician

2002 - 2003

The Cleveland Clinic Foundation, Cleveland, Ohio

- Trained internal medicine residents, interns, and medical students
- Attended on the inpatient medicine wards, primary care clinic, and pre-operative clinic performing medical consultations on national and international referrals.



- Supervised patient care team

Associate Physician

2000 - 2002

Shenandoah Internal Medicine, Augusta Medical Center, Virginia

- Practiced private practice Internal Medicine in rural Virginia
- Attended to patients in both the outpatient and inpatient setting
- Cared for patients in the Intensive Care Unit, Cardiac Step Down Unit, and performed cardiac stress testing

Publications

Peer-reviewed journal articles

1. Lathouwers E, Wong EY, Brown K, Baugh B, Ghys A, Jezorwski J, Mohsine EG, Van Landuyt E, Opsomer M, De Meyer S. Week 48 Resistance Analyses of the Once-Daily, Single-Tablet Regimen Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (D/C/F/TAF) in Adults Living with HIV-1 from the Phase III Randomized AMBER and EMERALD Trials. *AIDS Res Hum Retroviruses*. 2019 Oct 21;. doi: 10.1089/AID.2019.0111. [Epub ahead of print]
2. Eron JJ, Orkin C, Cunningham D, Pulido F, Post FA, De Wit S, Lathouwers E, Hufkens V, Jezorwski J, Petrovic R, Brown K, Van Landuyt E, Opsomer M. Week 96 efficacy and safety results of the phase 3, randomized EMERALD trial to evaluate switching from boosted-protease inhibitors plus emtricitabine/tenofovir disoproxil fumarate regimens to the once daily, single-tablet regimen of darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) in treatment-experienced, virologically-suppressed adults living with HIV-1. *Antiviral Res*. 2019 Oct;170:104543.
3. Naggie S, Fierer DS, Hughes MD, Kim AY, Luetkemeyer A, Vu V, Roa J, Rwema S, Brainard DM, McHutchison JG, Peters MG, Kiser JJ, Marks KM, Chung RT. Ledipasvir/Sofosbuvir for 8 Weeks to Treat Acute Hepatitis C Virus Infections in Men With Human Immunodeficiency Virus Infections: Sofosbuvir-Containing Regimens Without Interferon for Treatment of Acute HCV in HIV-1 Infected Individuals. *Clin Infect Dis*. 2019 Mar 28;. doi: 10.1093/cid/ciy913. [Epub ahead of print]
4. Orkin C, Molina JM, Negredo E, Arribas JR, Gathe J, Eron JJ, Van Landuyt E, Lathouwers E, Hufkens V, Petrovic R, Vanveggel S, Opsomer M; EMERALD study group. Efficacy and safety of switching from boosted protease inhibitors plus emtricitabine and tenofovir disoproxil fumarate regimens to single-tablet darunavir, cobicistat, emtricitabine, and tenofovir alafenamide at 48 weeks in adults with virologically suppressed HIV-1 (EMERALD): a phase 3, randomised, non-inferiority trial. *Lancet HIV*. 2018 Jan;5(1):e23-e34.
5. Cahn P, Kaplan R, Sax PE, Squires K, Molina JM, Avihingsanon A, Ratanasuwan W, Rojas E, Rassool M, Bloch M, Vandekerckhove L, Ruane P, Yazdanpanah Y, Katlama C, Xu X, Rodgers A, East L, Wenning L, Rawlins S, Homony B, Sklar P, Nguyen BY, Leavitt R, Teppler H; ONCEMRK Study Group. Raltegravir 1200 mg once daily versus raltegravir 400 mg twice daily, with tenofovir disoproxil fumarate and emtricitabine, for previously untreated HIV-1 infection: a randomised, double-blind, parallel-group, phase 3, non-inferiority trial. *Lancet HIV*. 2017 Nov;4(11):e486-e494.
6. Wyles D, Ruane PJ, Sulkowski MS, Dieterich D, Luetkemeyer A, Morgan TR, Sherman KE, Dretler R, Fishbein D, Gathe JC, Henn S, Hineostroza F, Huynh C, McDonald C, Mills A, Overton ET, Ramgopal M, Rashbaum B, Ray G, Scarsella A, Yozviak J,



McPhee F, Liu Z, Hughes E, Yin PD, Noviello S, Ackerman P for the ALLY-2 Investigators, Daclatasvir plus Sofosbuvir for HCV in Patients Coinfected with HIV-1. *N Engl J Med*. 2015 Aug 20;373(8):714-25.

7. Alcaide ML, Feaster DJ, Duan R, Cohen S, Diaz C, Castro JG, Golden MR, Henn S, Colfax GN, Metsch LR, The incidence of *Trichomonas vaginalis* infection in women attending nine sexually transmitted diseases clinics in the USA. *Sex Transm Infect*. 2015 Jun 12 pii: sextrans-2015-052010.
8. Metsch LR, Feaster DJ, Gooden L, Schackman BR, Matheson T, Das M, Golden MR, Huffaker S, Haynes LF, Tross S, Malotte CK, Douaihy A, Korthuis PT, Duffus WA, Henn S, Bolan R, Philip SS, Castro JG, Castellon PC, McLaughlin G, Mandler RN, Branson B, Colfax GN., Effect of risk-reduction counseling with rapid HIV testing on risk of acquiring sexually transmitted infections: the AWARE randomized clinical trial. *JAMA*. 2013 Oct 23;310(16):1701-10.
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10. Henn SL, Forrest GN, Febrile Neutropenia Associated with Painful Lesions of the Palms and Digits. *Clinical Infectious Disease*. 2006;43(6):747, 791-2.
11. Henn S, Bass N, Shields G, Crow TJ, DeLisi LE, Affective illness and schizophrenia in families with multiple schizophrenic members: independent illnesses or variant gene(s)? *Eur Neuropsychopharmacol*. 1995;5 Suppl:31-6.

Abstracts

1. Alt Olsen H, Sarkodie E, Coleman M, Davies M, Henn S, Fast Forward to Viral Suppression: A Nurse-driven Model for Facilitating Same Day Start of ARVs Following Reactive HIV+ Result or First-time Engagement in HIV Care. 2019, Association of Nurses in AIDS Care, Portland. Abstract #B-11.
2. Coleman M, Sarkodie E, Eggleston A, Kelley E, Henn S, Measuring Retention in Real World PrEP Programs; What is the best way to evaluate engagement with PrEP? 14th International Conference on HIV Treatment, Prevention, and Adherence, Miami. Abstract # 3381.
3. Alt Olson H, Sarkodie E, Coleman M, Davies M, Henn S, Fast Forward to Viral Suppression: Immediate Initiation of ARVs Following Reactive HIV+ Test Results or Engagement in HIV Care for the First Time at a Community Health Center in Washington, DC. 2019. 14th International Conference on HIV Treatment, Prevention, and Adherence, Miami. Abstract #5035.
4. Alt Olson H, Sarkodie E, Coleman M, Davies M, Henn S, Immediate Initiation of ARVs Following Reactive HIV+ Test Result or Engagement in HIV Care for the First Time at a FQHC in Washington. 2019. 6th Annual SYNChronicity Conference.
5. Walsh B, Coleman M, Dietrich M, Du Mond J, Jue J, Sadler M, Saperstein S, Wickham C, Henn S, Improvements in Engagement, Retention, and Viral Load Suppression in a Mobile Outreach Retention and Engagement (MORE) Project at a Community Health Center in Washington DC. 2017. 9th IAS Conference on HIV Science. Abstract #A-854-0225-05081.
6. Dieterich M, Coleman M, Du Mond J, Jue J, Sadler M, Saperstein S, Wickham C, Walsh B, Henn S, HIV+ Participants in the Mobile Outreach and Retention (MORE) Program in Washington, DC with Co-Morbid Mental Health and/or Substance



Abuse Diagnoses are Significantly Less Likely to Achieve Viral Suppression Despite Comprehensive Support. 2017 12th International Conference on HIV Treatment and Prevention Adherence, Miami. Oral Abstract #277.

7. Osinusi A, Wang C, Zhang X, Shivabesan G, Shivakumar B, Silk R, Doonquah L, Henn S, Teferi G, Masur H, Kottillil S, Fishbein D, Augmentation of Interferon signaling pathway by Nitazoxanide: A therapeutic strategy for HIV/HCV Coinfected Relapsers to Peg-interferon and Ribavirin therapy. 2012 19th Conference on Retroviruses and Opportunistic Infections, Seattle.
8. Silver D, Karnik G, Osinus A, Silk R, Stabinski L, Doonquah L, Henn S, Tefari G, Masur H, Kotillil S, Fishbein D, Liver Fibrosis in African Americans, Comparing HCV Mono-Infection with HIV-HCV Co-Infection. 2011 American Association for the Study of Liver Disease Conference, San Francisco.
9. Henn SL, Weekes E, Forrest GN, Methicillin Resistant Staphylococcus Aureus Bacteremia Treated with Linezolid: A Retrospective Review of Outcomes. 2006 46th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), San Francisco. Abstract #876.

Awards:

Outstanding Employee of the Year 2016, Whitman-Walker Health, selected by employees and the Employee Advisory Group

George McCracken Infectious Disease Fellow 2006, Interscience Conference on Antimicrobial Agents and Chemotherapy, San Francisco

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WHITMAN-WALKER CLINIC, INC., *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:20-cv-1630

**DECLARATION OF RAND PUMPHREY, D.MIN., LPC, BCC
SENIOR DIRECTOR OF BEHAVIORAL HEALTH, WHITMAN-WALKER HEALTH**

I, Randy Pumphrey, declare:

1. I am the Senior Director of Behavioral Health at Whitman-Walker Clinic, Inc., d/b/a Whitman-Walker Health (“Whitman-Walker”).

2. After earning a B.S. in American Studies, I received Masters of Divinity and Doctor of Ministry degrees from Wesley Theological Seminary. I initially worked as a Board Certified Chaplain at St. Elizabeth’s Hospital (which became the Commission on Mental Health Services for the District of Columbia and the Psychiatric Institute of Washington), and subsequently received my Professional Counselor Licensure in 1997.

3. I have worked in mental-health and substance-use-disorder treatment since 1984, initially as an intern at Washington Hospital Center, then with St. Elizabeth’s Hospital. In 1998 I became the Clinical Director of the Lambda Center, a joint partnership between the Psychiatric Institute of Washington and Whitman-Walker Clinic. I joined Whitman-Walker’s staff in 2007 as the Manager of Mental Health Services, and became Senior Director of Behavioral Health in 2015.

In addition to managing Whitman-Walker's behavioral-health services, I maintain a panel of patients for whom I provide direct care. A copy of my curriculum vitae is attached as **Exhibit A**.

4. I am submitting this Declaration in support of Plaintiffs' motion for a preliminary injunction to prevent the revised regulation under Section 1557, published by the U.S. Department of Health and Human Services ("HHS") on June 19, 2020 (the "Revised Rule"), from taking effect.

5. As the Senior Director of Behavioral Health, I oversee Whitman-Walker's robust portfolio of mental-health services, and substance-use-disorder-treatment services. Our mental-health services include individual and group psychotherapy, psychiatry, and peer counseling. For individuals struggling with substance misuse, we offer individual and group counseling and support, and Medically-Assisted Treatment (MAT). In 2019, we provided mental-health or substance-use-disorder-treatment services to 2,912 patients. Our psychiatrists, psychologists, licensed psychotherapists, and trained peer counselors have a special mission to the lesbian, gay, bisexual, transgender, queer and questioning (LGBTQ) community, and also to individuals living with HIV and their families and caregivers.

6. Many if not most of the individuals in our very diverse behavioral-health-patient population face considerable stigma and discrimination—as people living with HIV, as sexual or gender minority people, as people of color—and many of them struggle with internalized stigma and with acute or lower-level but persistent trauma. Many of them have experienced difficulty in finding therapists or other mental-health or substance-use-disorder professionals who are understanding and welcoming of their sexual orientation, gender identity, or struggles with HIV. We frequently receive phone calls and other inquiries from people seeking non-discriminatory, welcoming assistance with their substance use, depression, anxiety, or other challenges. Many of

these individuals have suffered from traumatizing encounters with hostile or disapproving health care professionals.

7. The Revised Rule's elimination of protections from discrimination based on gender identity, sexual orientation, transgender status, failure to conform with sex stereotypes, or LEP status, along with its expansion of religious exemptions, will result in more discrimination against LGBTQ patients, LEP patients, and patients living with HIV at other clinics, doctors' offices, hospitals, pharmacies, and other health care facilities outside Whitman-Walker. This increase in discrimination will harm the patients I serve and the patients whose care I supervise by directly harming their mental and behavioral health, discouraging access to mental and behavioral health care, and harming the patient-provider relationship, resulting in poor outcomes.

8. Experiencing discrimination in health care settings can have pronounced negative impacts on patients' mental and behavioral health. For example, a 2019 report by the Williams Institute at UCLA found that experiencing discrimination in health care settings is a unique risk factor for heightened suicidality among transgender individuals, a population already at heightened risk compared with the general population.¹ Conversely, nondiscrimination protections prohibiting discrimination in health care based on gender identity or transgender status have been associated with a decrease in suicidality among transgender and other gender minority individuals.² This is consistent with what I have observed over my years of experience in mental and behavioral health.

¹ See Jody L. Herman et al., The Williams Institute, *Suicide Thoughts and Attempts Among Transgender Adults* (2019), <https://williamsinstitute.law.ucla.edu/publications/suicidality-transgender-adults/>.

² See Alex McDowell et al., *Association of Nondiscrimination Policies with Mental Health Among Gender Minority Individuals*, JAMA Psych. (May 6, 2020), <https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2765490>.

9. The Revised Rule, by signaling that discrimination based on sexual orientation, gender identity, and transgender status is now permitted in health care settings, will on its own invoke increased fear and trauma among LGBTQ patients. Our clinic is likely to see an increased demand for mental-health services and behavioral-health services as a result. Patients will likely come to our care more distressed than they would otherwise due to the increased discrimination invited by the Revised Rule.

10. I and the providers and other behavioral-health staff that I supervise at Whitman-Walker have learned from patients about many incidents of discrimination or mistreatment based on a patient's actual or perceived sexual orientation, gender identity, or transgender status in other behavioral-health settings. For instance:

- a. A transgender teenager was hospitalized after a suicide attempt. Hospital staff refused to address the teenager by the young person's preferred pronouns and gender throughout the teenager's hospital stay. This was experienced by the teenager as disapproval and contempt for the young person's gender identity. This discrimination exacerbated the teenager's acutely fragile state when the teenager was so desperately in need of health care providers' support and health care services that were free of judgment.
- b. A facility that specializes in inpatient mental health and substance-use-disorder treatment, and which has explicit non-discrimination policies, nonetheless has significant trouble from nurses on weekend shifts (when the facility uses pool nurses rather than regular employees), who express strong disapproval of LGBTQ patients based on their religious beliefs or cultural upbringing. Despite the facility's non-discrimination policies, LGBTQ

patients encounter hostility, expressions of disapproval, and lack of responsiveness to their needs or requests from these nurses. For patients hospitalized for mental or substance-use disorders, these experiences can activate their disorders.

- c. As I previously noted, behavioral health staff that I supervise often receive calls or other communications from LGBTQ persons expressing desperation about finding a therapist or substance use professional who will not discriminate against them because of their sexual orientation or gender identity.
- d. Our behavioral-health providers who regularly interview our transgender patients to assess their stage of gender transition and readiness for gender-affirming surgical procedures, or who provide psychotherapy for these patients, report that the large majority of the patients they meet with—as many as four out of every five—report incidents of mistreatment or discrimination by health care providers and staff at hospitals, other clinics, doctor's offices, and other facilities.
- e. A patient who was employed by a church consulted his health care provider. One of the nurses called his church and told them he was gay and living with HIV. As a result, he was fired and lost his pension, forcing him to live on a severely limited income.

11. These incidents reveal that many health care providers and other staff harbor explicit or implicit biases against LGBTQ people. Because of legal requirements, health care facility non-discrimination policies, and professional norms, many of them have kept their personal beliefs and feelings in check. By signaling that discrimination based on sexual

orientation, gender identity, and transgender status is permissible under federal law, the Revised Rule is very likely to result in many more incidents of discrimination and greater harm to LGBTQ individuals struggling with mental health or substance use issues, including the patients whom I treat and whose treatment I supervise.

12. Behavioral-health treatment assumes, and requires, trust between the patient and provider, and full and frank disclosure by the patient of all potentially relevant information about their life, including their sexual orientation, sexual and affectional experiences, and gender identity. I, and the providers that I supervise at Whitman-Walker, frequently work with patients who have concealed some or all aspects of their sexual and affectional orientation or history, or gender identity, from non-Whitman-Walker therapists or other behavioral health providers, often to the patients' harm. The Revised Rule will very likely discourage LGBTQ people and others needing treatment from fully disclosing relevant information to their therapists or counselors, or to those helping them with substance-use issues, which will likely increase their distress and undercut the effectiveness of their treatment.

13. For persons with traditionally stigmatized sexual orientation—such as gay, lesbian, or bisexual people—or who are transgender or gender expansive, competent mental-health services, or services for treatment of substance-use disorders, require an accepting—indeed, an affirming—attitude towards their sexual orientation or gender identity by their provider. Discriminatory behavior, statements, or attitudes expressed by a provider are a tremendous barrier to effective care. It is critical that a patient feel empowered and supported in fully disclosing their sexuality and gender identity to their counselor, therapist, psychologist, or psychiatrist. Without a trusting patient-provider relationship and full disclosure of all possibly relevant feelings and facts by the patient, effective treatment is unlikely to be possible. This is critical for good medical care

as well. The kind of discrimination permitted by the Revised Rule will erode patient-provider trust among the patients our clinic serves, making it more difficult for patients at Whitman-Walker to achieve successful outcomes in their care.

14. The COVID pandemic has greatly increased the fear and apprehension in our community. Many LGBTQ people, including many of our patients, who have lived through the HIV/AIDS era are feeling re-traumatized by a new pandemic. During the first three months of the pandemic and related shutdown, we have seen a significant numbers of our substance use clients relapse. Many people's fear of encountering discrimination in health care settings has been heightened. Our substance use patients who are struggling and are LGBTQ have expressed reluctance to use city-operated treatment facilities because they fear hostility and discrimination from other patients and staff at those facilities. The issuance of the Revised Rule, with its message that LGBTQ discrimination is permitted, and its extensive, approving discussion of anti-transgender sentiments among health care providers, could not have come at a worse time.

15. In addition, our staff have experienced major operational challenges in responding to COVID-19 – including shifting behavioral-health services to telemedicine and temporary suspension of some services. This is a particularly difficult time to respond to increased demand for our services stemming from increased fear of discrimination encouraged by the Revised Rule.

16. I and Whitman-Walker provide referral services for patients who need specialist care that we do not provide—including inpatient behavioral health care as well as specialist medical care. We also receive many outside requests for recommendations for LGBT-welcoming, non-discriminatory therapists and substance-use professionals in the community. The Revised Rule will make it significantly more difficult for us locate and monitor appropriate referrals, and patients will suffer as a result. Even more concerning, our behavioral-health patients who may

need hospitalization for a mental-health or substance-use crisis, or may need specialist medical care, will be in greater danger of encountering discrimination at inpatient behavioral health facilities or when they seek medical care outside Whitman-Walker—which may make their care at Whitman-Walker more difficult and perhaps less successful.

17. All Whitman-Walker employees, and all volunteers who serve as peer counselors or otherwise are involved in any way with our behavioral-health services, are asked to commit to our mission, which is to be welcoming to and understanding of every patient, regardless of sexual orientation, gender identity, race or ethnicity, income or educational background, or life experience. We welcome staff and volunteers from a wide range of religious, spiritual, cultural, and philosophical perspectives, but patient needs must always be paramount. The overly broad religious exemptions in the Revised Rule threaten to substantially harm patients who are already vulnerable to stigma and discrimination. The message that health care providers' religious preferences or beliefs take priority over patient needs also violates fundamental professional ethical standards that apply to all licensed therapists, psychologists, psychiatrists, and substance-use-disorder-treatment professionals, including myself.

18. The Revised Rule removes or substantially weakens protections for LGBTQ individuals vulnerable to discrimination in health care settings. The inevitable increase in discrimination against LGBTQ individuals in health care settings that will follow from the Revised Rule will make it harder for us to care for our patients at the Whitman-Walker Clinic.

[Signature on next page.]

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 30 day of June, 2020.


Randy Pumphrey, D.MIN., LPC, BCC

EXHIBIT A

Curriculum Vitae of Randy Pumphrey, D.Min., LPC, BCC

Randy W. Pumphrey D.Min, LPC, BCC
2016 Perry Street NE
Washington, D.C. 20018
(Whitman Walker Health Office) 202-939-7679
Whitman-Walker email: rpumphrey@whitman-walker.org
Private Practice (cell) 202-369-4252
(e-mail) rpumphreylpc@verizon.net

PROFESSIONAL EXPERIENCE

Senior Director of Behavior Health at Whitman Walker Health (January 2015 to present)

- Works with the Chief Health Officer, Executive Director of the Health Center and the Chief Program Officer to strategically develop behavioral health programs, including recruitment and operational alignment with other health care services.
- Provides vision, leadership and strategic development to the behavioral health staff ensuring integration of services across the health center.
- Acts as member of Leadership Team, demonstrating leadership principles that encourage active feedback and an engaged workforce
- Develops and oversees programs for provision of behavioral health care, providing specific goals for implementation to other Behavioral Health staff.
- Monitors behavioral care outcome information, including: census data, Peer Review data, third-party related data and other metrics provided by Quality Improvement and Informatics to ensure appropriate response and program development.
- Monitors productivity, third-party revenue, and trends in health care delivery to ensure Behavioral Health programs are responsive to current payment methodologies and ready for future changes in health care reform.
- Collaborates with Administrative staff on various tasks including: grant funding, marketing and communication materials, development and fundraising, and community relations.
- Builds successful professional relationships with local community groups, business leaders, health care facilities and other organizations, acting as liaison and spokesperson for behavioral matters.
- Oversees the operations of all behavioral programs to ensure adherence to Whitman-Walker policies and compliance with local and Federal law.
- Ensures that behavioral health programs are being delivered by appropriately licensed and credentialed providers.
- Provides direct behavioral health care to clients
- Works with the Chief Medical Officer and Senior Director of Health Care Operations to strategically develop behavioral health programs, including recruitment and operational alignment with other health care services.
- Provides vision, leadership and strategic development to the behavioral health staff ensuring integration of services across the health center.
- Acts as member of Leadership Team, demonstrating leadership principles that encourage active feedback and an engaged workforce
- Develops and oversees programs for provision of behavioral health care, providing specific goals for implementation to other Behavioral Health staff.
- Monitors behavioral care outcome information, including: census data, Peer Review data, third-party related data and other metrics provided by Quality Improvement and Informatics to ensure appropriate response and program development.
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- Builds successful professional relationships with local community groups, business leaders, health care facilities and other organizations, acting as liaison and spokesperson for behavioral matters.
- Oversees the operations of all behavioral programs to ensure adherence to Whitman-Walker policies and compliance with local and Federal law.
- Ensures that behavioral health programs are being delivered by appropriately licensed and credentialed providers.
- Provides direct behavioral health care to clients

Behavioral Health Manager for Mental Health at Whitman Walker Health (August 2007 to December 2014.)

- Hire and Manage all Mental Health clinicians
- Provide individual administrative and clinical supervision to eight staff therapists and Master Level clinical interns
- Conduct individual and group psychotherapy (group topics include – Sexual Compulsion in Gay Men, Long Term Survivors of HIV, Stress Management with HIV)
- Manage department budgets
- Manage grant budgets
- Conduct community workshops on a variety of Mental Health issues and topics
- Operate as Deputy Behavioral Health Director in absence of Behavioral Health Director
- Provide administrative direction and supervision to the Mental Health Department

Private Practice – Psychotherapy and Spiritual Directions (October 2007 to present)

- Individual and couple's therapy with focus on co-occurring disorders, relationship issues – including love addiction and love avoidance, sexual compulsion, anxiety, depression, loss and grief, HIV, trauma and issues related to sexual orientation acceptance.
- Spiritual Direction – work in tandem with other therapists to deal with psycho-spiritual conflicts with their clients. Deal directly with client struggling to find meaning and acceptance through a variety of spiritual practice.

Director of The Lambda Center: Behavioral Healthcare for the LGBTQ community.

A partnership between The Psychiatric Institute of Washington and Whitman-Walker Clinic (September 1998 to July 2005 and The Psychiatric Institute of Washington from July 2005 to August 2007.)

- Hire and supervise all clinical staff
- Direct an interdisciplinary treatment team working with lesbian, gay, bisexual and transgender adult clients.
- Manage the operation of an Inpatient detoxification and mental health stabilization program, a Partial Hospitalization program, and an Intensive Outpatient program.
- Supervise Master's level interns in Counseling Psychology and Community Counseling as well as Master level counseling staff for LPC licensure.
- Conduct individual, group psychotherapy, a full spectrum of co-occurring recovery groups, process oriented topic groups as well as skills groups dealing with life management skills, cognitive impairments, emotional regulation, living with HIV/AIDS, spirituality, grief and loss, relational issues, family dynamics, sexual identity integration and gender identity integration.
- Orient all new hospital staff on issues of cultural competency.
- Successfully led Lambda Center through three Joint Commission Surveys, DCRA annual surveys, CMS surveys, APRA certification surveys and Tricare surveys.
- Education and community relations through seminars, national conferences, grand rounds and workshops that teach mental health and addiction treatment professionals about therapeutic interventions with the gay, lesbian, bi-sexual and transgender communities.

Chaplain

The Psychiatric Institute of Washington, Washington, D.C., (July 1986 –March 2005).

- Served as consultant with hospital administration to create an integrated spiritual program for a free standing Psychiatric hospital.
- Conduct weekly worship as well as special holiday celebrations for the Children's unit, the Adolescent unit and the Adult units.
- Facilitate weekly spiritual resource groups, process groups, dual diagnosis step groups, and conduct individual pastoral counseling.
- Consult with treatment staff regarding the religious and spiritual issues of clients within a variety of specialized programs including — intensive care, dual diagnosis, Gay and Lesbian, the Center for Post Traumatic Syndrome and Child / Adolescence.
- Assess the spiritual needs of clients upon referral.
- Designed assessment tool used by the hospital.
- Grand Round presentations "Mind, Body, Spirit -- The Healing Formula," "The Emerging Spirit - The Integration of Spirituality in Mental Health Care," "Spirituality in the Treatment of Gay and Lesbian persons."

Administrative Chaplain for the Acute Psychiatric Hospital

Commission on Mental Health Services, Saint Elizabeths Campus, D.C., (July 1987 - August 1998).

- Coordinate and manage pastoral staff providing spiritual care for the Acute Psychiatric Hospital.
- Conduct individual and group pastoral counseling and spiritual direction to clients suffering with a full range of psychiatric disorders and dual diagnosis.
- Educate and counsel persons living with HIV infection/AIDS, addiction recovery and sexual identity integration.
- Teach interns and residents therapeutic and sensitivity issues with lesbian/gay/bisexual/transgender persons.
- Facilitate and lead workshops for hospitals and churches dealing with "Spirituality and Recovery," "Living with AIDS," "Meditation," "Visitation and Referral," and "Sensitivity to the Mentally Ill."
- Create group therapy forum for staff who had survived recent loss to work through issues of grief and loss.
- Conceptualized and implemented new pastoral care procedures to increase our direct patient care and maximize pastoral effectiveness.
- Monitor clinical record keeping.
- Clinical experience in Acute Care, Dual Diagnosis, Geriatric, Forensic, Long Term Chronic Care and Out-patient Day Programs. Clinical Supervision of pastoral interns and residents.
- Train, delegate, and schedule pastoral staff; residents, and interns.
- Perform weekly worship, preach, and distribute the Sacraments.

Pastoral Assistant

First United Methodist Church, Bradbury Heights, Washington D.C., (Oct. 1984-May 1985).

- Designed and implemented an educational program for youth.
- Participated on all church committees.
- Created and preached a special Advent worship series and taught the Lenten Bible study.

Youth Minister

Korean United Methodist Church of Washington D.C., (Oct. 1981 -Jan. 1983).

- Designed a Christian education program for trans-generational children.
- Conducted a weekly English worship service.
- Created and counseled a United Methodist youth group.
- Trained Korean parents as Sunday school teachers.

EDUCATION

Doctorate of Ministry; Wesley Theological Seminary, September 1991 to May 1997.
Thesis: "A Spiritual Recovery Program Informed by Process Theology."

Clinical Training: Clinical Pastoral Education

- The Commission on Mental Health, Washington, D.C.
2 Basic units, 2 Advanced units, and 9 Supervisory units, June 1985 – August 1988.
- The Washington Hospital Center, Washington, D.C.
1 Basic unit, September 1984 - May 1985.

Masters of Divinity; Wesley Theological Seminary, Sept. 1981 to May 1985.
Focus on Pastoral Care and Counseling.
Chair of the Arts Committee and Co-creator of the Liberation Resource Committee.

Bachelor of Science; Towson University, Towson Maryland, September 1979 to May 1981.
Major: American Studies with a concentration in American literature and Human development,
Honors: Cum Laude.
Outdoors adventure club, Orientation department team leader.

Associates of Arts Degree

Anne Arundel Community College, Maryland, Sept. 1977 to May 1979.
Major: American Studies
Honors: Magna Cum Laude

Additional continued education in a variety of mental health issues including – CBT, Ethics, Post Induction Therapy, Inner Child integration and Shame and Pain Reduction, Sexual Compulsion, Love Addiction, and Trauma

CREDENTIALS and PROFESSIONAL ASSOCIATIONS

- Licensed Professional Counselor in the District of Columbia. PRC1134 Exp.12/31/1998.
- Board Certified by the Association of Professional Chaplains, May 1990 (Retired Status)
- Ordained Elder in the United Methodist Church, June 1989.
- DC Behavioral Health Association Board, Secretary second term

LANGUAGES

Proficient at intermediate level signed English

REFERENCES:

UPON REQUEST

CERTIFICATE OF SERVICE

I hereby certify that on January 19, 2021, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Joshua Dos Santos
JOSHUA DOS SANTOS